



National Farmers' Federation

**Consultation Regulation Impact
Statement on
A National Scheme for Assessment,
Registration and Control of Use of
Agricultural and Veterinary Chemicals**

11 April 2011

Prepared by Dr Sam Nelson



National Farmers' FEDERATION

Member Organisations



CANEGROWERS



COTTON
AUSTRALIA



Goat Industry Council
of Australia Inc.



GrainCorp



RICEGROWERS' ASSOCIATION
OF AUSTRALIA INC



RIDLEY



*The Pastoralists'
Association of
West Darling*



Victorian Farmers
Federation



WOOLPRODUCERS
AUSTRALIA

Contents

Policy Options and Impacts of Options	4
Governance	5
Assessment and Registration	6
Efficiency and effectiveness in the assessment and registration process	6
Risk framework	6
Efficiency in assessment and registration.....	6
Assessment and use information	7
Facilitating registration of low risk products.....	7
Facilitating access for minor uses.....	8
Access to high risk chemicals.....	8
Other aspects of the operating environment	8
Enhancing the provision of expert advice.....	8
The precautionary principle	9
Permissible uses.....	10
General access categories and permits.....	10
Permissible uses for crops.....	10
Veterinarians' prescribing rights.....	10
Management of the chemical portfolio.....	11
Supplier compliance – importers, manufacturers and retailers/distributors	11
Control of Use	11
A national system of use controls – monitoring, auditing, surveillance and traceback to ensure safe use.....	12
A national system of use controls – record keeping	12
Training and Licensing.....	12
Fee-for-reward users`	12
Farmers and other occupational users.....	13
Sales personnel and advisors	13

POLICY OPTIONS AND IMPACTS OF OPTIONS

Chemicals are an important tool in underpinning the productivity of many farming systems. It is important to ensure the agricultural industries have access to a suite of chemicals for different purposes in order to manage their production systems. Many of the Australian agricultural industries compete in International markets, and it is important that Australian industries have access to the tools which will allow them to remain competitive in these markets. It is important that Australia's agricultural and veterinary chemical regulatory framework also look at processes and incentives to encourage new chemicals to be brought to the Australian market as they are developed and made available internationally. It also needs to be recognised that while Australia exports significant quantities of agricultural produce we are a relatively small market for agricultural chemicals. Effective mechanisms must be in place to allow Australia's agricultural industries to access the chemicals, particularly where there is a market or regulatory failure which means that chemical registrants do not have the incentive to register chemicals – particularly for 'minor-uses'. Fundamental in all of this is the need to ensure safe and effective chemicals continue to be available to chemical users while minimizing the cost of regulation.

The focus of the regulatory impact statement paper appears to be strongly on the need for regulation, rather than on achieving outcomes or alternatives to regulation. The key outcomes that the agricultural industries are looking for from these changes in chemical regulation proposed in the paper include:

- Encouraging the introduction of new chemicals onto the Australian market
- Encouraging the registration of chemicals for 'minor use' applications
- Ensuring chemical registrants, chemical users and the Australian public have confidence in the regulatory system
- Encouraging the safe use of chemicals
- Ensuring that the process that underpins chemical assessment and registrations is efficient and effective, but also transparent.

Finally, the agricultural industries are also looking for opportunities to avoid or reduce any increase in regulatory burden or costs associated with increased regulation.

The National Farmers' Federation (NFF) supports reform of chemical regulation, and recognises that there are many areas that could be improved to address the outcomes listed above. However, these reforms need to be undertaken with clear outcomes in mind, learning from past experience with current regulation and not merely with the purpose of change for its own sake.

The paper does not provide a very clear discussion on the impact of costs or benefits from the various options or how the options presented may interact. Industry has significant concerns that the implications of changes in chemical regulation will have in terms of the costs of chemicals, but also on the availability of chemicals. It is important that costs are not increased without significant benefits, and that the implementation of recommendations should have a positive impact on the introduction of new chemicals on the Australian market, as well as addressing longstanding issues such as minor use. Without this information it is very difficult for industry to make informed comment on the

impact of the proposed regulation. It would appear that many of the costs set out in the options relate to government process and administration costs, and the Department should have access to this information and be able to make an assessment of the likely cost impact of the measures proposed but also the improved output generated through additional resources.

GOVERNANCE

The NFF supports a nationally consistent and coordinated methodology for the assessment, registration and regulation of agricultural and veterinary chemicals. National consistency and coordination between Commonwealth and State/Territory governments, statutory bodies and industry groups, presents an opportunity to achieve a streamlined and user-friendly regulatory structure. However, it is important to recognise and preserve the strengths of the current system, including its capacity to recognise and respond to local differences. NFF members have noted the usefulness of being able to work with State and Territory authorities, particularly to work through issues related to minor use and provide guidance to industry. Until a system is in place that makes a significant difference to overcoming minor use issues, it is likely that local departments will add significant value to this process. A weakness of the current assessment and registration system is the location in Canberra which can make it difficult and costly for individual user industries to engage and discuss regulatory issues. The agricultural industries, as users of chemicals, also have limited opportunities to engage with the regulatory authority to discuss issues such as labelling and registration through the consultation forums currently available.

The current inconsistency and ambiguity in agricultural chemical regulations is caused, in the NFF's view, by a lack of congruity in government approaches at Federal and State levels. The resulting excessive red tape burden (administrative overheads, and the wasting of valuable time and financial resources – which impact productivity) makes compliance a complex and laborious process for farmers. The NFF believes that the COAG regulatory reform process presents an opportunity to incorporate national standards under State legislation, with the aim of simplifying and clarifying compliance.

For these reasons the NFF supports options which deliver consistency in the assessment and registration functions as well as consistency in the delivery of regulatory functions.

A range of options are presented which offer various degrees of harmonization and models for the delivery of services under Governance (section 5). The NFF supports the principle of greater harmonization but in practice there will need to be a transition to these arrangements as the regulatory issues are dealt with and the regulatory environment becomes clearer to stakeholders. The options presented represent different levels of sophistication in the harmonization process and the NFF does not have a clear position on the ultimate model, although it is important that State and Territory Governments maintain roles in the delivery of control of use functions. Current responsibilities need to be maintained with the potential to move to a more harmonized model of operation and governance once the outcome of the proposed reforms to regulation are known and improvements from the reform measures have been demonstrated.

6 ASSESSMENT AND REGISTRATION

6.1 Efficiency and effectiveness in the assessment and registration process

6.1.1 Risk framework

The NFF supports a transparent evidence based approach to the assessment and review of risks related to agricultural and veterinary chemicals. It is important that this process is based on sound science which is used to underpin the evidence base for decision making and that there are clear processes for reviewing and accounting for the various risks. Clear definitions and descriptions of the way risks are dealt with under the risk framework would help to demystify the process among the community and industry. It is important that the risk frameworks recognise the operational environment in which chemicals are used, and the opportunity for chemical users to manage these risks.

Only one option has been presented on the implementation of a risk framework, and it is not clear how much work is required to deliver the option, the cost, if it would result in delays in the registration of new chemicals, if chemicals currently going through the registration process would be further delayed and the extent it would impact on the current use of agricultural and veterinary chemicals. Significant time and resources may be required to document the risk frameworks and publish this information. It is not clear what this cost would be, and it is unclear how this would be paid for. Because of the public good outcomes from the proposed framework, and to ensure there is transparency, there is a role for public funding in the development of the framework as well as the oversight of its operation.

While the NFF supports the option in principle, as it improves transparency, it is not clear what the implications of implementing the option would be for costs and the timing of assessment of chemicals. It is also not clear how the implementation of other options, such as the use of the precautionary principle (6.2.3) would interact with this option and the associated costs or delays in assessments.

6.1.2 Efficiency in assessment and registration

NFF is not a chemical registrant, and is not directly involved in the registration and assessment process. However, Australian farmers need a system of chemical registration that facilitates the introduction of new chemicals onto the Australian market in a timely and cost efficient manner. Australian farmers compete in International markets, and it is important that they have access to the tools which allow them to produce safe fresh produce in a cost effective manner.

The costs incurred by registrants in the registration and assessment process and any inefficiencies in the process are passed onto farmers by chemical registrants in the form of increased chemical prices and delays in accessing newer chemicals. The costs of registration may also influence the decisions to register a chemical in Australia by a chemical registrant. As a consequence of these considerations, the NFF would support the implementation of measures to improve the efficiency of the assessment and registration process.

The NFF is not in a position to provide comment on the details of the options presented, but notes that the assessment and registration process should be efficient and effective to reduce the cost of the process, but also transparent. Applicants should be clear on the process and their responsibilities as registrants. The NFF notes that where a chemical is intended to be used in agricultural applications then efficacy data and trade risk should be considered in the registration process.

6.1.3 Assessment and use information

As mentioned earlier, the NFF supports the principle of greater consistency in information provided to chemical users. Consistency in efficacy descriptions across jurisdictions has the potential to reduce labelling costs, and the savings from this efficiency may be passed onto chemical users. Consistency in labelling also reduces confusion for chemical users and is likely to ensure the safe use of chemicals in compliance with label instructions.

The two options, including a common approach to product efficacy across jurisdictions (option 1) and improved availability of information by publishing labels on the internet (option 2), could be implemented in tandem. However, the options create some questions. If option 1 is successful in improving consistency in data on labels, then some of the value from option 2 may be reduced. Option 2 also relies on users having access to the internet, which is not ubiquitous in rural and regional Australia¹, and may create confusion on the validity or legal standing of on-package labels versus the labels published on the internet. More information is required on the cost of option 2 and the potential merits of the proposal.

6.1.4 Facilitating registration of low risk products

The NFF has continued to call for the registration of newer, safer chemicals on the Australian market. The NFF supports the development of a registration pathway which promotes the registration of low risk products and encourages chemical registrants to bring these products to market. Any registration pathway that facilitates the registration of low risk products should not cause delays or reduced resourcing to review and assess chemicals which are not regarded as low risk. On this basis the NFF supports option 1 in principle, but notes that no other options have been presented.

The Consultation Regulation Impact Statement describes a range of strategies and processes that may improve the registration process, and it is not clear if a facilitated registration process would add significant benefits beyond those of the other strategies and processes outlined.

If Government is to proceed down this path it would be advised that consultation take place with the agricultural industries to determine what product grouping may be appropriate. Product grouping would need to be described in a meaningful way to industry to ensure the chemicals are used correctly.

¹ Australian Bureau of Statistics (2006) 8146.0.55.001 - Patterns of internet access in Australia (<http://www.abs.gov.au/AUSSTATS/abs@.nsf/Lookup/8146.0.55.001Main+Features12006?OpenDocument>)

6.1.5 Facilitating access for minor uses

Under the current arrangements, off-label and minor-use mechanisms have been an important and valuable mechanism which allows Australian farmers access to the chemicals for what are regarded as ‘minor uses’. For example, Australia’s rice industry, which exported rice with a total export value of \$82 million in 2007/08, is a regionally based and geographically confined industry which requires access to off-label and minor-use chemicals. Some of these chemicals are registered for use in other industries or regions and the cost of obtaining separate registration for use in the relatively small rice industry is prohibitive. This situation is common across a large number of industries in Australia.

The current arrangements have led to significant issues for the agricultural industries and a range of different strategies have been employed by the States and Territories to help facilitate access to chemicals by the agricultural industries. A proliferation of different regulations has resulted and led to significant differences across the jurisdictions.

Effective arrangements to facilitate access to chemicals for minor uses are a high priority for the agricultural industries, and for this reason the NFF supports option 1 to facilitate inclusion of minor uses on labels. Improved arrangements to encourage chemical registrants to increase the range of uses included on labels would reduce the demand for minor use permits and off-label arrangements. Any new scheme to facilitate access to chemicals for minor uses should be regularly reviewed in consultation with both chemical registrants and chemical users to ensure the measures are effective and delivering outcomes for user industries, but also to monitor the extent to which there is continued unmet demand for chemical products within users.

6.1.6 Access to high risk chemicals

The NFF supports a nationally consistent and coordinated methodology for the assessment, registration and regulation of agricultural and veterinary chemicals, and this includes the need for greater consistency in the way that high risk chemicals are able to be accessed and used across jurisdictions as outlined in Option 1. However, the implementation of this option may result in significant costs for users operating in particular jurisdictions in order to undertake training to meet competency requirements, depending on what competency standard is defined.

6.2 Other aspects of the operating environment

6.2.1 Enhancing the provision of expert advice

The NFF supports the need for processes which can inform a continuous review and improvement of the review and assessment process within the APVMA. As users of chemicals which are subject to this process we have an interest in ensuring that chemicals are reviewed and assessed in a timely and efficient manner. It is important that the APVMA has the flexibility to implement changes in response to the recommendations of the panel. While the capacity of these panel members to understand the scientific principles behind the review and assessment of chemicals is important, a key aspect of

their work is ensuring that these principles are adhered to while delivering an effective and efficient assessment and review process.

The suggestion to reduce the overheads of APVMA through the use of expert advisor(s) rather than through the convening of an advisory board as outlined in Option 1 is supported in principle however further information is sought on how this might alter the costs of the APVMA's operation and its effectiveness. The ability for APVMA to take advice from a range of different experts, and for the AVPMA to be able to seek out a range of experts with relevant expertise and experience, is important in assisting the APVMA in its functions and improving the outcomes of its decision making. To ensure there is confidence in the proposed system, the process to identify, select and appoint experts should be transparent as well as there being clarity on the subject and nature of the advice they are to provide. It is appropriate that chemical users be included among the experts that are engaged.

6.2.3 The precautionary principle

The use of the precautionary principle to underpin regulation of chemicals is inappropriate and the NFF has significant concerns with both of the options presented. In general terms the precautionary principle prescribes that a lack of scientific certainty should not be a justification for failing to act if there is the prospect of serious or irreversible damage. However, a number of definitions of the precautionary principle exist and the terms used to describe the precautionary principle can be poorly defined. In addition the precautionary principle has been used in a number of different contexts, which serves to cause confusion and uncertainty which does not benefit chemical registrants, users or the broader community.

Implementation of a precautionary approach will result in potential bias to err on the side of minimizing risks without sufficient regard for costs of this action. For example, excessive testing of a new chemical may be required, or overly-cautious recommendations for controls made that are out of proportion to the risks involved. This will generate greater uncertainty about the use and availability of chemicals among users, and is likely to further reduce the appetite of chemical suppliers to register chemicals.

An approach underpinned by scientific risk assessment and risk management is a more appropriate and pragmatic mechanism for considering the risk, and is embodied in the current APVMA approach. Risk assessment is a scientifically based process consisting of four steps: hazard identification, hazard characterization, exposure assessment, and risk characterisation. Each of these steps is based on the best information available and allows for risks to be identified and actively managed and, where needed, selecting appropriate prevention and control options. The NFF notes that a more explicit documentation and management of risks is proposed as part of the regulation reforms under 6.1.1. If the options outlined in 6.1.1 are adopted it is unclear what additional value the adoption of the precautionary principle, as explained here, would add or how the processes would interact and what the resultant costs and benefits would be.

The NFF believes that rather than the adoption of a precautionary approach, the risks and the way risks are dealt with should be explicitly described. An explicit description of the risks and the mechanism for dealing with the risks would improve the transparency of

decision making and would be of greater benefit to chemical registrants, users or the broader public.

6.3 Permissible uses

6.3.1 General access categories and permits

As discussed earlier in 6.1.5, the NFF strongly supports arrangements to facilitate access to chemicals for minor uses. Incentives and process changes are required which address the current market failures and encourage the registration of chemicals for minor uses. For this reason the NFF does not support Option 3 to retain the status quo, and supports both Options 1 and 2 as mechanisms which may improve the current situation.

Option 1, which proposes the establishment of a set of broad permissible uses on a basis of assessed risk, is an opportunity to improve this situation and a new mechanism which may assist in encouraging registrations. The potential benefits and improvements from Option 2, which focuses on improved efficiency of assessment, are not as clear. The agricultural industries have continued to highlight that the difficulties experienced with generating chemical registrations for minor use are in part an issue of market failure. Improved efficiency is only one part of the solution, and needs to be considered in conjunction with: changes in regulation to provide registrants with greater certainty on issues related to process and intellectual property (as discussed under 6.1); changes to the regulatory framework (such as Option 1 (6.3.1)); but also options for Government support to programs similar to the United States of America IR-4 minor use program to generate data in light of the market failures.

It is important that access to chemicals for minor uses be improved in order to gain the confidence of industry and allow a move away from the status quo (Option 3). A transition to the arrangements described under Option 1 will take time, and this process and timeframe has not been clearly described.

6.3.2 Permissible uses for crops

As outlined in 6.1.5 and 6.3.1 above, the NFF supports the proposal to develop mechanisms which assist in allowing chemical users to access the chemicals they need, and addresses issues of market failure which reduces the likelihood that chemical registrants will register chemicals for minor uses. The NFF understands that this is a complicated issue, and there is not likely to be a single solution in the short term.

A number of different frameworks to permit access to chemicals for minor use exist across the Australian States and Territories, each with its own set of risks and benefits. NFF members have had different experiences with these frameworks, and there is not a consistent view on the most appropriate path forward. As outlined under 6.3.1 above, it is seems likely that arrangements to improve availability of chemicals for minor uses will need to be put in place as a pre-cursor to the development of greater consistency in access arrangements.

6.3.3 Veterinarians' prescribing rights.

As described earlier, the NFF supports a nationally consistent and coordinated methodology for the assessment, registration and regulation of agricultural and veterinary chemicals. In line with this principle the NFF supports Option 1, to harmonise veterinarians prescribing rights across jurisdictions to ensure legitimate user access to chemicals without compromising the assessment and registration system of veterinary chemicals.

6.4 Management of the chemical portfolio

The NFF has significant concerns regarding the proposal to put in place a review process for registered chemicals. The NFF is aware that under existing chemical review arrangements the APVMA has the flexibility to review registrations when new research or evidence has raised concerns about the use or safety of a particular chemical or product. Fundamental concerns exist in the establishment of a new process which may duplicate, add minimal value or reduce flexibility in the existing processes and mechanisms in place, as well as concerns that Australia may be establishing a system which is ‘out of step’ with the international standards. There are likely to be limited benefits to end-users from the additional costs of this process, and the proposed arrangements will also increase the workload of the APVMA. Opportunities to strengthen the current framework should be explored before implementing a new policy framework and review process.

Australian farmers are very much aware that the agricultural chemical industry is a global industry, and differences in Australian regulation may deny Australian farmers access to useful and effective farm chemicals which are available to our International competitors. The experience of many industries in gaining access for chemicals for ‘minor-use’ is that where a market for chemicals is small, chemical registrants may not be able to justify the cost to register chemicals and go through re-registration if they are unable to get the commercial returns from their products. The NFF also fears that generic chemicals, or chemicals which may be close to coming off patent, or losing data protection, will be lost from the market as the chemical registrants would not see the commercial case in generating data and evidence to underpin continued registration. The loss of these chemicals may have significant implications for farmers, for example the loss of valuable control options or removing options for the management of chemical resistances.

For these reasons, the NFF supports Option 3, to maintain the status quo.

6.5 Supplier compliance – importers, manufacturers and retailers/distributors

The NFF recognises that chemical users, as well as the community more broadly, may benefit from improved compliance in the supply of chemicals. For this reason, Option 1 which provides a complete set of compliance powers for the registration authority is supported in principle. However, the Regulation Impact Statement provides no information as to the extent of the problem, the cost to users and the community from the compliance issues or the cost of the proposed resolution. Further information on the extent and cost of non-compliance is required in order to understand the magnitude of the issue.

7 CONTROL OF USE

7.1 A national system of use controls — monitoring, auditing, surveillance and traceback to ensure safe use

The NFF supports greater consistency of control-of-use regimes, on the basis that it will improve the consistency with which controls are applied and enforced, and reducing potential confusion for chemical users. On the basis of the improved consistency in regulation there is the potential to decrease costs to suppliers and users of agricultural and veterinary chemicals in some instances, and at the same time provide greater certainty and clarity over the respective responsibilities and resourcing for regulatory activities. On this basis the NFF supports the further development of Option 1, the establishment of a national program for monitoring residues and contamination. However, there are significant differences in the control-or-use arrangements that currently exist nationally, and the implementation of new arrangements will change the costs for users in some regions. Greater clarity is required on the control-of-use arrangements being developed and the cost implications for chemical users in different jurisdictions and industries, including the cost of auditing and surveillance programs.

It is important that these controls are established and implemented to reflect the changes in risk that result from the implementation of other recommendations in this regulatory impact statement. Improved availability of chemicals for ‘minor-use’ applications and greater consistency in labeling will make it easier for chemical users to comply with labels and regulations. In line with these behavioral changes the degree of monitoring required, including auditing and surveillance, needs to be reviewed on an ongoing basis to ensure it remains appropriate and that costs are managed.

7.2 A national system of use controls — record keeping

As with other options presented in this discussion paper, the NFF supports greater harmonization of regulation and accompanying requirements for record keeping as outlined under Option 1. However, the NFF notes that there is currently significant variation in record keeping requirements. For this reason the development of a nationally consistent approach should be done in consultation with chemical users with a view to ensure the reporting burden and cost is minimized while the benefits of reporting are realized.

In seeking to develop a system of harmonized record keeping it is important to recognise that variations in record keeping have developed for a number of reasons, including regulatory compliance but also compliance with private quality assurance programs. It is important that any system developed for record keeping has the flexibility to allow the records to be consistent with existing quality assurance systems to avoid duplication of record keeping. In looking to develop a record keeping framework the Government should consult with States and Territories as well as industries involved in quality assurance programs to understand the formats currently in existence and ensure the potential for duplicate records being avoided. Similarly, strategies for auditing and monitoring should be developed in consultation with industry to ensure they are effective and do not duplicate existing programs.

8 TRAINING AND LICENSING

8.1 Fee-for-reward users

The NFF supports the principle for greater consistency in licensing requirements for fee-for-reward users. At present these arrangements vary between jurisdictions, and further information is required on how fee-for-reward users may be defined and the fee-for-reward user services which would be covered. The level of competency which needs to be demonstrated must also be considered as well as the cost of the transition to new arrangements as this may impose significant costs in different jurisdictions. Based on the information available the relative costs of implementing Options 1 or 2 are also not clear, and further information is required before the most appropriate model of implementation can be identified.

8.2 Farmers and other occupational users

The NFF supports effective measures which improve farm safety, and recognises that farmers should be able to demonstrate the capability to handle and use chemicals properly. This has good outcomes for farmers, and is important for consumer confidence in domestic and export markets. Australia must find export markets for 60 per cent of the food we produce. To do this Australia must maintain its reputation for producing clean, high quality food free of all contaminants and especially free of chemical residues. Training needs to be designed for farmers and in consultation with farmers, with practical outcomes in mind. On this basis the NFF supports Option 1, to set nationally agreed competency requirements for users, with the requirements to be based on risk and to be consistent with the levels assumed in the assessment and registration process.

At present training requirements vary significantly between States and Territories. Anecdotal evidence from members indicates that mandatory training for agricultural and veterinary chemical users does not deliver significant benefits beyond ensuring that a minimum level of knowledge is met. Feedback from NFF members indicates that in order to operate effectively and efficiently, modern farmers are taking on the responsibility of learning about the use of chemicals and their chemical application equipment. A greater focus should be placed on making information freely accessible and available to farmers, and that the format of the information is appropriate. In these circumstances farmers will take on the responsibility of keeping themselves informed.

While the role of accredited trainers is recognised, there is significant scepticism of their effectiveness and the quality of the training delivered where training is a mandated requirement. A range of options should be considered, including self-auditing schemes rather than mandatory updates. The training needs and strategies to address these needs will need to vary from industry to industry, and between regions. A national strategy needs to be able to cope with different competencies and have measures in place to deal with issues such as operators from non-English speaking backgrounds.

As outlined in 8.1 above, transition to any new arrangements may require the implementation of training programs in some jurisdictions which may impose some cost to farmers and other occupational users and this will need to be considered.

8.3 Sales personnel and advisors

The NFF notes that farmers are obliged to follow directions as set out in labels and permits. Sales personnel provide advice to chemical users; however the quality of this advice is known to vary which leads to the risk of poor advice and ultimately the potential for poor choice of products to be made. While advice from the point of sale can be useful in making decisions between products, compliance ultimately rests with the chemical user. For this reason Option 3, to recognise an industry scheme to accredit advisers and sales persons would provide benefits to industry through improved quality of advice.