



National Farmers' Federation

Submission regarding a National Scheme for Assessment,
Registration and Control of Use of Agricultural and Veterinary
Chemicals

to the Australian Pesticides and Veterinary Medicines Authority
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Member Organisations



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1. Introduction

The NFF understands the importance of the assessment, registration and regulation of chemicals, and welcomes the opportunity to consider the restructure and improvement of current practices. Farmers are committed to using chemicals responsibly and conscientiously. The NFF looks forward to continued engagement in this process to secure efficient, viable and sensible outcomes for Australian farmers. In this submission we have outlined a number of key areas of interest to the NFF and our membership.

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 for regulating the use of chemicals. However, it is important to recognize and preserve the strengths of the current system, including its capacity to recognize and respond to local differences.

The current level of inconsistency and ambiguity in agricultural chemical regulations is caused, in the NFF's view, by a lack of congruity between government agencies both 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.

The NFF endorses the vertical integration of agricultural and veterinary chemical control-of-use regimes into a National Registration Scheme, provided that duplication with state and territory regulatory controls is identified and eliminated. There are two reasons for this endorsement. Firstly, integration will eliminate areas of duplication between national and state/territory regulatory regimes and secondly, it will improve the consistency with which APVMA controls are applied and enforced, reducing current confusion in this area. It is expected that these outcomes will decrease costs to suppliers and users of agricultural and veterinary chemicals, and at the same time provide greater certainty and clarity over the respective responsibly and resourcing for regulatory activities.

Whilst NFF appreciates the opportunity to respond to the discussion paper, we note that the period allowed for stakeholders to develop a response fell over Christmas and the New Year. A number of NFF members have noted that this has severely limited their ability to participate in the process, consult with their respective members and provide an informed response to the Product Safety and Integrity Committee. Chemical regulation is a significant issue for Australian farmers, and NFF and its members look forward to future opportunities for consultation as a National Scheme for assessment, registration and control of use of agricultural and veterinary chemicals is further developed.

2. The National Registration Scheme

Agricultural and veterinary chemicals are a critical tool for modern farmers, and they are used in many elements of farm management and operation. Agricultural and veterinary chemicals assist farmers to underpin production, manage the risks to their livelihoods from pest and disease outbreaks, as well as maintaining the environment through the

control of weeds and facilitating the adoption of conservation farming practices. Australia needs a National Registration Scheme for chemicals that supports the efficient and safe production of agricultural commodities. A national registration scheme can be delivered in a number of ways, but it is essential that the system is established in a way that ensures it will be efficient and effective. The NFF has significant concerns that the effectiveness of current arrangements are not adequate, and have left Australian farmers disadvantaged.

Off-label and minor-use mechanisms have been an important and valuable mechanism which allows Australian farmers access to the chemicals they need to produce safe food in an environmentally responsible manner. The need for these, or similar, arrangements to exist cannot be stressed enough. 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 minor-use arrangements have been poorly resourced and this has caused delays in assessments. These delays place entire agricultural industries, worth millions of dollars, at risk from farmers who may resort to the illegal use of chemicals to save crops from preventable weed, disease and pest infestation. The lessons from the current arrangements must be learnt in establishing any new assessment and registration arrangements.

3. Issues for Consideration in Developing a National Framework

The development of a national framework has benefits in that it may provide consistency of rules and regulation. However, there needs to be consideration given to the benefits that exist within the current system. A move to a national framework should not be accompanied by increased red tape and inflexibility because of administrative advantages. At present regional administration by States and Territories allows farmers and other chemicals users to work with authorities to address the needs of regional production systems, the pest and disease challenges that occur through seasonal variation, as well as the introduction and development of new farming systems.

A national framework which provides consistency in the assessment, registration and regulation of chemicals has advantages. For farmers the proposed framework may resolve cross border issues which place limitations on the purchase of chemicals, and lead to confusion in the way chemicals may be used. There is also an expectation that a national framework would allow greater coordination between assessment and operational aspects related to the control of chemicals, and improved communication across government.

A mechanism needs to be in place to ensure that chemical users are able to provide feedback on the operation of the framework, and that the agencies responsible have the operational flexibility to respond to the needs of users to improve efficiency and effectiveness. The needs of chemical users vary from region to region and with the production systems in place. A national framework needs a mechanism where it can convene advisory groups which reflect the needs and issues of typical chemical users. Without these mechanisms the system is unlikely to be able account for the diversity of industries and geographical regions it is seeking to service and regulate, and will not have the confidence of the industry it works with.

The use of the precautionary principle to underpin regulation of chemicals is inappropriate. 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 environmental damage. Implementation of a precautionary approach will result in potential bias to err on the side of minimizing risks, and will not have 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 amongst users, and is likely to further reduce the appetite for 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 characterization. Each of these steps is based on the best information available and allows for risks to be identified and actively managed and, if needed, selecting appropriate prevention and control options.

4. Assessment, Registration and Access to Chemicals

The processes that underpin the assessment, registration and access to chemicals must be transparent and authorities must be accountable for the timely and effective administration of these processes. Authorities must work with chemical suppliers and chemical users to develop benchmarks for performance that recognize the commercial environment in which chemical suppliers and users operate. It is important that performance benchmarks are meaningful, and that authorities are accountable to meeting these benchmarks.

As more information becomes available about the interactions between chemicals and the environment, it seems likely that the assessment of chemicals and the data required to underpin the assessment will become increasingly complex and the cost of collecting data to understand efficacy will grow. The costs and barriers incurred by chemical suppliers seeking to have chemicals assessed and registered need to be clearly understood, and measures taken to facilitate the introduction of new chemicals. This includes an examination of the costs of assessment and registration, along with regulatory issues such as data protection. However, farmers, as chemical users, benefit from the availability and reduced price of generic chemicals and the competition this introduces into the market. In turn, Australian and international consumers also benefit from reduced food prices. The cost trade-offs between the availability of generic chemicals and appropriate protection for chemical suppliers seeking to register products needs to be better understood to understand the implications of changes to data protection arrangements for chemical suppliers seeking to register chemicals. These trade-offs and the costs involved need to be examined in consultation with both chemical suppliers and chemical users.

The opportunity to use international data in the registration of chemicals, and the development of relationship with agricultural and veterinary chemical regulators in Canada, the United States of America and the United Kingdom should also be explored as a means of facilitating registration, particularly as a means of assisting the registration of chemicals for minor-use applications. However, we note that due regard of Australian conditions and differences in production systems should be taken into consideration when considering the appropriateness of using approved foreign data. If the use of foreign data

is implemented, a review of the effectiveness of the system should occur within two to three years of its introduction to confirm that it is working satisfactorily.

Trade risk and efficacy must continue to be included in the assessment and registration process conducted by the APVMA. Trade is critical to Australia's agricultural export industry. Assessment of trade risk from chemical usage is most appropriately undertaken by the agency responsible for chemical assessments and registration. For example, the livestock industry relies upon the work undertaken by the APVMA to allow export slaughter intervals are included in product labels, providing mechanism for trade risk to be managed by the industry. The risk of trade disruption and the economic and reputational damage to Australian agricultural exports, which totalled \$27.5 billion in 2007-08, have significant implications for Australian agricultural industries.

5. Control of Use

Compliance activities to support control of use arrangements should reflect the level of risk posed by chemicals, and that the approach to compliance should vary regionally to reflect the types of chemicals and the likely level of chemical use. For agricultural industries the significant variation in the level of monitoring and compliance activity that takes place as a consequence of the current arrangements creates a risk for human and environmental health, along with economic and reputational damage to the industry. There is an opportunity for the regulatory authority to consult with chemical users to understand patterns of use, and the potential for non-compliance.

Where possible government should work with industry members to ensure that industry understands and is able to respond appropriately to control-of-use requirements. This partnership approach offers benefits in that industry may be better informed - and may be able to innovate to improve the way particular chemicals are used - and that through the development of sound relationships with industry, industry members can assist in identifying cases of non compliance. The use of penalties is more likely to create distrust between industry members and authorities, increasing the level of resourcing required to deliver the same level of compliance.

6. Competencies, training, accreditation and licensing

The NFF supports effective measures which improve farm safety, and recognizes that farmers should be able to demonstrate the capability to handle and use chemicals properly. This has good outcomes for farmers, and is good for consumer confidence and exports. Australia must find export markets for 60 per cent of the food we produce. To do this Australia must maintain its reputation in 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.

At present training requirements vary significantly between States and Territories. 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.

Whilst the role of accredited trainers is recognized, 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.

7. Possible Structures for a National Regulatory Scheme

Any administrative structure to deliver a National Regulatory Scheme should be developed to ensure that the regulatory scheme is effective, and that costs to industry and tax payers are minimized. In order to ensure that the scheme delivers the needs of chemicals users, mechanisms should be in place to ensure forums exist to allow chemicals users to provide feedback on the effectiveness of the Scheme and opportunities for improvement.

The development of a National Regulatory Scheme would require a sound understanding of how the current system is administered at a regional level, and there needs to be significant discussion with users and authorities to understand the level of flexibility required and identify how the flexibility can be delivered under a new system. It is unlikely that this level of detail can be drawn out through the broad consultation currently been undertaken, particularly given the tight timelines issued for responses.

Mechanisms to ensure a nationally consistent approach to compliance should be considered. The NFF understands that compliance is currently the responsibility of a range of State and Territory based organizations, and as a consequence the approach to compliance and the resourcing dedicated to this activity vary significantly. The regulatory reform process presents an opportunity to develop greater consistency and incorporate national standards under State legislation, with the aim of simplifying and clarifying compliance. This would also an opportunity to develop a national approach to control of use and compliance activities, as well as ensuring a consistent and transparent mechanism for funding these activities adequately. Compliance activities are best undertaken by local authorities who have established reputations and relationships with industry. The level of resourcing and compliance activity should account for the risk of non-compliance, with the risk reviewed regularly to ensure the outcome of safe agricultural produce is achieved.

8. Funding Issues

The regulation of chemicals needs to be appropriately funded in order to ensure that the chemical users have access to the agvet chemicals they require to operate, and that the interest of the public and the environment are recognized. There is an expectation that the regulator will be appropriately resourced to undertake its responsibilities, in an efficient and effective manner. To this end, it is important that the cost of the regulators function and structure be considered during the development of the regulatory scheme, to understand future costs and resourcing requirements.

The resourcing provided to the APVMA should reflect the magnitude of the task that is being undertaken. Anecdotal evidence indicates that the APVMA is currently under resourced to review and assess the volume of chemicals submitted for registration.

Similarly, there are concerns that the compliance activities undertaken by a number of the States has been insufficiently resourced. These circumstances undermine confidence of both chemical suppliers, users and the broader public in the effectiveness of the regulatory scheme. Resourcing of the APVMA must be reviewed and considered as part of the development of a National Regulatory Scheme. One off costs, such as improved information technology systems, should also be recognized and resourced if these investments can improve the efficiency and effectiveness of the chemical assessment and registration in the longer term.

An effective chemical regulation scheme delivers significant benefits to the public, as well as chemical users and suppliers. To this end costs of performing these functions should be properly attributed, and these costs need to be transparently reported to both government and industry stakeholders. Concerns have been raised regarding the costs of administration and reporting requirements to government (including the preparation of Ministerial briefs, answering questions on notice, preparation of portfolio budget statements) and the potential subsidization of these costs by charges to industry. Industry expects that its contribution to the registration and assessment of chemicals should be used for these purposes in line with Government cost-recovery guidelines, not absorbed by bureaucratic costs. Clear and transparent reporting of these costs is required for industry to have confidence in a National Regulatory Scheme.

The need to access chemicals for ‘minor-use’ applications is a significant challenge for Australian farmers. As mentioned earlier, Australia farmers need a National Registration Scheme for chemicals that supports the efficient and safe production of agricultural commodities. However, when compared with European, American and Asian production systems the value of Australian production systems, and the difference in our environment, simply make it un-economic for chemical suppliers to justify the cost of registering chemicals for many uses. This market failure is partly brought about by the cost of the assessment and registration process required to ensure health and environmental risks are understood and managed, as well as the policy setting established by government. Under these circumstances it is entirely appropriate for government to intervene and provide support for the assessment, registration and regulation of agricultural and veterinary chemicals.

9. Is Cost Recovery of Control of Use Appropriate?

The NFF has significant concerns with the proposal to cost recover monitoring compliance, investigation and enforcement. The outcomes of control of use activities have significant public good elements, minimizing illegal and inappropriate use of agricultural and veterinary chemicals to ensure that the Australian public enjoys safe and clean food and that the quality of the Australian environment is maintained.

Australian farmers find it increasingly difficult to absorb increased costs, and are not able to pass additional costs on to consumers. Australian farmers compete in international markets, where prices are set by competitors. Whilst Australian farmers benefit from a reputation for producing healthy and clean produce, they face the commercial reality that markets are driven by price. Australia’s agricultural competitors may not be subject to the same control of use arrangements, or their control of use arrangements continue to be publically funded. The proposal to cost recover control of use does not recognize the international environment in which Australian agricultural industries operate.

The assessment and registration process for agricultural and veterinary chemicals establishes guidelines to ensure health and environmental risks through the application of chemicals are minimized. It is only through improper or illegal use of chemicals that health and environmental impacts are likely to occur. However, it is likely to be difficult, expensive and inefficient to design a cost recovery framework that is able to distinguish between users who may improperly or illegally use chemicals and users who apply chemicals according to guidelines. It is also not clear what mechanisms could be established to provide incentives for chemical users to operate according to guidelines in order to reduce their costs. The majority of farmers should not be disadvantaged by other users who improperly or illegally use chemicals.

The discussion paper does not make it clear how a cost recovery framework may be applied, and without a clear indication of this it is difficult to determine the potential implications. Increased costs of chemicals may result in reduced use of chemicals, resulting in increased incidence of pests, weeds and diseases, which may result in increased incidence of environmental impacts off-farm. Chemical users may increase their use of generics, which may act as a further disincentive for chemical suppliers to register chemicals. Farmers may also look to control pests, diseases and weeds through traditional means using tillage or burning which have serious consequences for soil organic matter and sustainability. There is the chance that increased cost may result in improper usage of chemicals, but this may be to reduce dosage resulting in the potential for increased incidence of resistance to agricultural and veterinary chemicals – an outcome that would reduce productivity of the industry.

