RESPONSE TO THE PRODUCTIVITY COMMISSION DRAFT RESEARCH REPORT ON CHEMICALS AND PLASTICS REGULATION

Department of Agriculture, Fisheries and Forestry

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1. GENERAL COMMENTS

The Department of Agriculture, Fisheries and Forestry (DAFF) has a national leadership role in the development and implementation of agricultural and veterinary (agvet) chemicals policy. It provides the chair and secretariat to the Product Safety and Integrity Committee (PSIC) which provides policy advice to the Primary Industries Ministerial Council (PIMC) on agvet chemicals policy issues.

Commonwealth and state/territory governments all have a role in providing policy advice on agvet chemicals to PIMC through their membership of PSIC. Under the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS), responsibility for administration of the legislation governing the national regulator (the Australian Pesticides and Veterinary Medicines Authority (APVMA)) rests with the Commonwealth (DAFF) in consultation with the states/territories through PSIC. The states/territories are responsible for legislation controlling the use of those chemicals after the point of retail sale. Therefore, the comments in this submission are made in the context of the implications for PSIC, as the policy development body, its individual members and its stakeholders. In drafting the submission, DAFF has consulted state/territiory PSIC members but notes that most have contributed to a whole-of-government response in their particular jurisdictions which, in some cases, may present different views to those put forward in this submission.

The institutional arrangements proposed by the Productivity Commission (PC) for key chemicals regulatory frameworks, identify roles and responsibilities and provide an overarching framework within which the existing, separate, chemicals regulatory frameworks can operate more effectively and efficiently. With respect to strategic policy development and oversight (Level 1)**,** the proposal to establish a Standing Committee on Chemicals (SCOC) will help to address the fragmentation, duplication and overlap of chemicals regulations by providing a formal mechanism for more co-ordinated and, therefore, better informed policy development across all the specific areas of responsibility of the individual Ministerial Councils involved in chemicals regulation. At the same time, it will allow each of the Ministerial Councils to continue to develop policy, drawing on the expertise and knowledge of their agencies and stakeholders. It will also provide a mechanism for generating awareness and understanding of programs and initiatives already in place that could be used to meet common risk management objectives across other chemicals regulatory frameworks.

The proposal that states and territories continue to have responsibility for administration and enforcement of chemical regulations, but in accordance with national standards (Level 4), will help to address the anti-competitive and cost impacts of having different requirements/standards which are enforced differently in each jurisdiction. The PC Report suggests that hazard and risk assessment (Level 2) is best undertaken by an independent national body of experts and should be separated from standard setting and risk management (Level 3) which should also be undertaken by technical experts within the constraints determined by policy set by the relevant Ministerial Council. However, it is not clear from the Report, what the benefits of

separating these processes would be. It is noted that the PC does not propose this model for the APVMA but rather that the APVMA should continue to have responsibility for both functions.

This submission does not include comments on the hazard and risk assessment and the standards setting and risk management levels. It is expected that the APVMA will provide detailed comment on these aspects in its submission. Rather, the comments are confined to those recommendations which have implications for agvet chemicals regulation at the levels of policy development and oversight (Level 1) and administration and enforcement (Level 4) as follows

- the establishment of the Standing Committee on Chemicals
- the National Registration Scheme for Agricultural and Veterinary Chemicals (NRS)
- setting maximum residue levels (MRLs)
- implementing the Global Harmonisation System for the classification and labelling of chemicals (GHS)
- workplace hazardous chemical labelling
- the management of chemicals in the environment
- chemicals of security concern.

Although making no specific recommendation in relation to minor use policy, the PC supports efforts to address this issue, provided they can deliver net public benefit. Comments are provided on the impacts of minor use on the efficiency and effectiveness of the NRS and suggests some ways in which government could assist in addressing this issue.

2. COMMENTS ON THE RECOMMENDATIONS

Draft Recommendation 3.1

Subsequent to the COAG Ministerial Taskforce on Chemicals and Plastics Regulation having completed its reference, the Commonwealth, states and territories should establish, under the Australian Health Ministers' Conference, a Standing Committee on Chemicals, comprising representatives of all ministerial councils that have responsibility for chemicals regulation. It would:

- provide an ongoing forum for assessing:
  - the consistency of chemicals-specific policy settings across the various areas of concern, including public health, workplace and on-farm safety, transport safety, environment protection and national security
  - the effectiveness and efficiency of the overall chemicals-specific regulatory system
- address emerging issues, such as nanotechnology
- oversee the consistent application of chemicals hazard and risk-assessment methodologies
- make recommendations for specific actions by individual ministerial councils.

Comments

According to the draft Report, the Standing Committee on Chemicals (SCOC) would need to report to a particular ministerial council for administrative reasons. It recommends that, because many chemical regulatory issues impact on human health in one way or another, SCOC should report to the Australian Health Ministers' Conference.

It is accepted that there is a need for SCOC to report to ministers to make them accountable and to ensure that there is the political will for appropriate action to be taken. If SCOC is given responsiblity for the implementation of agreed regulatory reforms, it may be necessary for SCOC to report, initially, to COAG. However, since responsibility for chemicals policy decision making in the longer term would continue to rest with the various ministerial councils (the Australian Health Ministers' Conference, the Primary Industries Ministerial Council, Environment Protection and Heritage Council, Workplace Relations Ministerial Council, the Australian Transport Council and COAG for chemical security issues), the proposal for SCOC to report to the Australian Health Ministers' Conference could be seen as an additional, and unnecessary, level of reporting and decision making. Further, although individual ministerial councils would ultimately make policy decisions with respect to their particular chemicals regulatory framework, if SCOC were to report to the Australian Health Ministers' Conference, there may be a perception that decisions are driven only by the interests of Health Ministers and their stakeholders.

This could be overcome by having SCOC report to all of the above Ministerial Councils. The SCOC would identify which Ministerial Council(s) is(are) required to take action and which is(are) only required to note the action being recommended. A similar approach was adopted when the policy responsibilities of the former Agricultural and Resource Management Council for Australia and New Zealand (ARMCANZ) were split between two new Ministerial Councils – the Primary Industries Ministerial Council and the Natural Resource Management Ministerial Council. In cases where issues may require decisions/action by both Councils, papers are developed for joint consideration. Where natural resource management and environment protection issues overlap, they are dealt with by the Natural Resource Management Ministerial Council and the Environment Protection and Heritage Council in a similar way.

For this approach to be effective, each of the Ministerial Councils would have to agree that their chemicals policy advice would now be provided through SCOC rather than their current standing committee. To avoid SCOC being too unwieldy, it is proposed that its membership would include only two representatives of each Ministerial Council.

Ministerial Councils will need to be confident that policy proposals put forward by SCOC have taken into account their particular interests and those of their stakeholders. Therefore, it is proposed that advice to SCOC be provided by sub-committees established under each Ministerial Council. These sub-committees would develop chemicals policy advice on behalf of each Ministerial Council and, in doing so, would be required to consult with each other to ensure that the implications for all portfolios and their stakeholders are identified and taken into account when developing policy proposals. Because each Ministerial Council would have only two representatives on the SCOC, these sub-committees would need to include representation from each of the states/territories so that all jurisdictions contribute to the development of national policy advice. They would also need to include appropriate technical advisers.

Such sub-committees already exist under some Ministerial Councils. For instance, agricultural and veterinary chemicals policy advice is provided to the Primary Industries Ministerial Council by the Product Safety and Integrity Committee which includes representatives of each jurisdiction and receives technical advice from the APVMA and CSIRO. Where similar sub-committees don't already exist, they would need to be established. In addition, the SCOC would be able to establish working groups/taskforces to address particular issues.

This approach provides a formal mechanism for ensuring cross jurisdictional and cross portfolio co-ordination in the development of chemicals policy. As a result, the implications of proposals would be better understood and policy development would, therefore, be better informed. In addition, duplication and overlap of regulatory requirements would be minimised.

SCOC will need administrative/secretariat support. However, this could be provided in ways other than reporting to a particular ministerial council as proposed in the draft report. For instance administrative/secretariat support could be provided by the

agency of the SCOC chair. To ensure that this would not impose unreasonable demands on the resources of a particular agency, the chair/secretariat role could be rotated on a regular basis – perhaps annually. This would have the added advantage of avoiding the possibility that SCOC could be perceived as being aligned with a particular Ministerial Council or stakeholder group.

Draft Recommendation 4.6

The National Registration Scheme for agricultural and veterinary chemicals should be extended to cover regulation of agricultural and veterinary chemical use after the point of retail sale, provided:

- the new national regime contains appropriate exemption provisions and is administered at state and territory level, to allow adequate flexibility to address local issues
- there is a commensurate reduction in regulatory burden at state and territory level.

Comments

The National Registration Scheme (NRS) for agricultural and veterinary chemicals is a partnership between the Commonwealth and state/territory governments which is underpinned by an inter-governmental agreement (IGA). Under the IGA, the APVMA has responsibility for the regulation of chemical products up to, and including, the point of retail sale while the states/territories are responsible for regulations governing the use of those products once they are sold. This is mainly done through control of use legislation in each state/territory.

As such, the NRS already includes the regulation of use after the point of retail sale. Therefore, it is assumed that the intention of the recommendation is not for the NRS to be extended to cover the regulation of agricultural and veterinary chemical use after the point of retail sale but for the APVMA to assume responsibility for those functions currently undertaken by the states/territories as part of the NRS - noting that it is proposed that state/territory agencies would continue to administer national control of use regulation on behalf of the APVMA by way of service level agreements with the APVMA.

The main objective of the NRS is to manage the health, environment and trade risks of agvet chemical use. There are three main ways in which these risks are managed: through the instructions/information included on the label; through label enforcement; and through conditions imposed on users such as licensing, training, record keeping and neighbour notification.

Although not part of the NRS, the states/territories administer other legislation which allows them to take action to manage the consequences of the use of agvet chemicals after they have been used. For example, to manage a trade risk associated with the use of an agvet chemical (such as a residue in produce), some jurisdictions can issue trade protection orders whereby, amongst other things, a person can be stopped from selling affected produce. States/territories also administer legislation designed to

manage the risks of chemical use generally. This legislation impacts upon agvet chemicals and covers areas such as environmental protection, public and environmental health, dangerous goods, poisons and occupational health and safety.

In considering this recommendation, only the regulation underpinning the NRS is discussed.

Label Instructions/Information

The label includes risk management, efficacy and advisory instructions/information and is, effectively, the standard that has to be complied with by users. The instructions/information are based on a risk assessment undertaken by the APVMA. The inclusion of risk management instructions is designed to ensure that the human health, environment and trade risks of agvet chemical use are managed. Efficacy and advisory information is included so that users know how to use the product to best effect.

Label Enforcement

Responsibility for ensuring that agvet chemical products are used according to label rests with the states/territories. There are differences in the way that the labels are enforced. For instance, some jurisdictions enforce all aspects, whilst others only enforce those considered essential for managing the risks. This means that some jurisdictions allow certain uses that are not included on the label (off-label use). For example, whilst the label may specify the crop on which the chemical can be used and the pest to be controlled, most jurisdictions allow products to be used on a different pest on the same crop since this would only potentially affect product efficacy and, therefore, is not essential for managing the health, environmental and trade risks.

Conditions Imposed on Users

States/territories determine the conditions imposed on users. These differ from jurisdiction to jurisdiction. However, there appears to be no clear justification, from a risk management point of view, for users in different jurisdictions to be subject to different requirements. Logically, similar groups of users would pose similar risks regardless of the jurisdiction in which they live – for example, those from non-English speaking backgrounds and those who apply chemicals close to high risk areas such as population centres, waterways and environmentally sensitive fauna and flora.

How the Effectiveness and Efficiency of the NRS Could Be Improved

Improvements to the NRS could be made in a number of areas, including the three noted above. For instance a nationally consistent approach to label enforcement and the conditions imposed on users would reduce the anti-competitive effect of having different regulations in different jurisdictions. For those businesses which operate in more than one jurisdiction (such as those involved in the aerial application of

agricultural chemicals), it would reduce the costs of having to meet different regulations in different jurisdictions.

In addition, the regulatory burden on users would be minimised if conditions were imposed only when it can be demonstrated that they are essential for managing the risks and if enforcement focused only on those aspects of the label which must be complied with to deliver the risk management objectives of the NRS - because the efficacy and advisory information on the label is not directed at risk management, its enforcement imposes unnecessary costs on users.

Efforts have been made, through the Primary Industries Ministerial Council's Product Safety and Integrity Committee (PSIC), to achieve a nationally consistent approach to label enforcement and to the conditions imposed on users. However, as noted in DAFF's initial submission to the PC, it has proven difficult to fully deliver these outcomes for various reasons, including difficulty in getting unanimous agreement to policy approaches. This means that differences continue to exist.

The recommendation to transfer responsibility for regulation controlling the use of agvet chemicals after the point of retail sale from the states/territories to the Commonwealth would address these differences. It would deliver nationally consistent risk management outcomes**,** given that only the APVMA would be determining the conditions users must meet as part of its risk assessment – noting that the APVMA would continue to consult the states/territories in undertaking the risk assessment. It would also ensure that decisions on the conditions are justifiable on the basis that they are essential for risk management. This is consistent with an approach already endorsed by PSIC whereby the APVMA, rather than the states/territories, will determine the conditions for accessing higher risk chemicals in consultation with registered training organisations. However, the states/territories will continue to have responsibility for enforcement, including authorising persons to have access to such chemicals.

With regard to enforcing only the risk management instructions of the label, it would need to be made clear which instructions need to be enforced – the current wording sometimes creates uncertainty as to which are the risk management instructions. Further, the instructions would need to be worded in a way that makes them unambiguous for enforcement purposes, for example, by using words such as 'must' instead of 'should'.

Improvements could also be made in relation to operational aspects of the APVMA such as the timeliness and cost of registration and the registration of products which impose a low risk to public health the environment and trade. The PC Report notes that the APVMA is already taking steps to address these issues in response to the recommendations of the 2006 Australian National Audit Office Performance Audit of the APVMA and through work being progressed by PSIC to provide for quicker and less costly registration for low risk products. Work by PSIC to clarify the scope of products regulated by the APVMA is another area where changes have been agreed that will reduce the cost of regulation.

Whilst not the subject of a specific recommendation, the PC Report notes that accelerating the pace of the APVMA's Chemical Review Program would also deliver

improved risk management outcomes because it would ensure that the formulation of, and the label instructions/information for, agvet chemical products which were registered by the states/territories before the formation of the NRS, continue to manage the risks.

Minor use is another area where the effectiveness and efficiency of the NRS could be improved. This is discussed in more detail in Part 3 of this submission.

Implementation/Implications

The states/territories may have concerns about transferring responsibility for control of use to the Commonwealth. This option was considered, and rejected, at the time the NRS was established on the basis that this was a major change and that control of use would best be administered by the jurisdictions since they were closer to users and had a greater knowledge and understanding of local conditions. Given that the NRS has been operating for over a decade, it may now be appropriate to reconsider this issue to take full advantage of the significant effectiveness and efficiency benefits which resulted from the establishment of the NRS.

In doing so, it is important to recognise that the states/territories would continue to have a role in the regulation of agvet chemicals. Their involvement is essential for the reasons noted in the paragraph above. The arrangements proposed in response to Recommendation 3.1 (which deals with policy oversight) provides for the states/territories to continue to have a role in national agvet chemical policy development through PSIC. In addition, the PC Report proposes that states/territories would continue to administer and enforce control of use regulations through service level agreements with the APVMA.

The Report notes that establishing a single, national regime could lead to a loss of flexibility in addressing local issues and that it has been suggested that some variability between states/territories would always be warranted due to the differences in geography, climate and primary industry structure. However, it needs to be made clear where this flexibility/variability would be required.

As noted earlier, there seems to be no justification, from a risk management point of view, for variations between jurisdictions in the conditions imposed on users (such as training, licensing and neighbour notification). These conditions are designed to manage the risks posed by users rather than manage variations in risk as a result of differences in geography or climate or primary industry structure. It would seem more appropriate for the latter differences to be considered when determining the label instructions and/or by issuing permits for off-label and emergency use rather than by allowing jurisdictions to deviate from regulatory requirements on the grounds of unique local circumstances. Having said that, states/territories need to be able to respond quickly to local incidents. This flexibility can be built into the regulatory scheme through mechanisms such as emergency orders which can be issued by the states/territories.

In transferring responsibility for control of use to the Commonwealth, consideration needs to be given as to how the increased compliance and enforcement costs would be

met. One option is for the Commonwealth to provide funding from consolidated revenue. Alternatively, given that the states/territories currently fund their own activities for controlling the use of agvet chemicals, they may be prepared to share the funding with the Commonwealth through the Primary Industries Ministerial Council cost sharing arrangements.

Another option is for the APVMA (as a cost-recovered agency) to recover the compliance and enforcement costs by increasing the fees and levies which manufacturers currently pay to fund the APVMA's activities - noting that cost increases to manufacturers are likely to be passed on to users. For some time, manufacturers and users have been asking governments to put in place nationally consistent regulations for controlling the use of chemicals, claiming that they face unnecessary costs by having to meet different regulations in different jurisdictions. They have also lobbied for the compliance and enforcement activities to be made nationally consistent and at a level which provides them with assurance that chemicals are not being misused – otherwise there is a risk of chemicals being removed from the market. However, it is not certain that the benefit to manufacturers and users of transferring responsibility for control of use to the Commonwealth will be sufficiently large that they would be willing to bear the cost of doing so.

Draft Recommendation 5.9

Maximum residue limits set by the APVMA, which take account of dietary impacts using methods agreed with Food Standards Australia New Zealand (FSANZ) and the Australian Government Department of Health and Ageing, should be automatically incorporated into the Australia New Zealand Food Standards Code. Any decision to the contrary by FSANZ and the Australia and New Zealand Food Regulation Ministerial Council should be based on a cost– benefit analysis and be reported publicly.

Comments

The Blair Review of Food Regulation, published in August 1998, noted that the involvement of both the NRA (now APVMA) and ANZFSA (now FSANZ) in setting MRLs in food creates unnecessary delays. Therefore, it was recommended that legislation and administrative processes of the two agencies should be amended to facilitate streamlined MRL setting. COAG noted that this would be addressed in establishing FSANZ as the new national domestic food standards setting agency.

As noted in the PC Report, some progress has been made in that recent legislative amendments have been made to reduce the time lag between APVMA and FSANZ decisions. However, the fact that the Food Regulation Ministerial Council still has to approve an MRL before it can be included in the Food Standards Code, can add up to an estimated six to nine months before a farmer, who is complying with the MRL determined by the APVMA, can legally sell their product.

This recommendation would increase the efficiency of the system whilst, at the same time, ensuring that the safe food objectives of the Food Standards Code continue to be met.

Draft Recommendation 6.2

The Commonwealth, state and territory governments should replace the existing systems of regulation of workplace hazardous substances and dangerous goods with a single system of regulations for the classification, labelling, provision of material safety data sheets and risk assessment for all workplace hazardous chemicals. The new system should be based on the Globally Harmonised System of Classification and Labelling of Chemicals (GHS).

Australia should not implement the new system until our major trading partners have implemented the GHS. In this context, the European Union has announced that it intends to move to a GHS-based system in 2015.

Comments

PSIC has established a working group to consider the implications of the GHS for agvet chemicals. It has been noted that adoption of the GHS hazard classification might be feasible since it is closely aligned with that currently used in Australia. However, further consideration is being given to determine whether adoption of the GHS label elements will enhance our current risk-based approach for labelling agvet chemicals. The working group also believes that the GHS should not be implemented for agvet chemicals in Australia ahead of our major trading partners.

Draft Recommendation 6.3

Any new system for workplace hazardous chemicals labelling should recognise labels approved by APVMA as being sufficient for workplace requirements.

Comments

Continuation of the arrangement whereby the Australian Safety and Compensation Council (ASCC) recognises the APVMA labelling code as appropriate for meeting the requirements of its occupational health and safety legislation, is consistent with the move to rationalise existing chemicals regulation. This is a good example of where cross portfolio co-ordination and recognition of existing programs/initiatives can reduce the regulatory burden on industry.

Having said that, it will be important to ensure that the APVMA labelling code continues to accommodate the needs of OH&S regulators. The new institutional arrangements proposed in recommendation 3.1 will provide a mechanism to facilitate such consultations.

Draft Recommendation 8.1

The Environment Protection and Heritage Council (EPHC) Chemicals Working Group should continue to assess the need for a national framework for the management of chemicals in the environment.

If this work demonstrates that such a framework would improve effectiveness and efficiency, the Commonwealth, state and territory governments should negotiate an intergovernmental agreement to create an independent standard-setting body reporting to the EPHC.

- This body would develop standards for the environmental risk management of chemicals that the states and territories would adopt by reference, and have the power to ban or phase out chemicals, subject to appropriate cost–benefit analysis.
- Members of the environmental risk management standard setting body should be appointed based on their qualifications and experience. The body should be constituted to reflect the broader public interest and have the ability to appoint advisory bodies as necessary.

Comments

It is acknowledge that Environment Ministers should have a greater role in chemicals regulation/standards setting. However, since the APVMA already has the power to ban or phase out chemicals (see first bullet point in the recommendation) it is assumed that this recommendation applies to industrial chemicals only but this should be stated and made absolutely clear.

Draft Recommendation 9.1

A nationally uniform approach to conducting security checks for access to security sensitive ammonium nitrate should be implemented, irrespective of other harmonisation measures. This process should be managed by the Australian Government, through AusCheck. The information should be shared across jurisdictions by the establishment of a database that reports current, refused or revoked security clearances.

Draft Recommendation 9.2

State and territory governments should consider the following improvements for achieving greater national harmonisation of the security sensitive ammonium nitrate (SSAN) regulations:

- removing major inconsistencies in reporting requirements
- basing storage requirements on the internationally agreed physical properties of SSAN, provided security controls are met

- ensuring that a single security plan can be lodged for transporting SSAN nationally
- making licence durations nationally consistent
- regulatory agencies committing to, and reporting on, timeframes for assessing licence applications.

Draft Recommendation 9.3

State and territory governments should not add any additional security sensitive chemicals to the current security sensitive ammonium nitrate regulations.

Draft Recommendation 9.4

Australian governments should establish an agreed framework for assessing the security risks and appropriate control measures associated with chemicals of security concern. This framework should incorporate strong governance arrangements, underpinned by an intergovernmental agreement, that ensure control measures are implemented consistently across jurisdictions. Once established, this framework should be used to re-examine the controls on ammonium nitrate.

Comments

DAFF supports these recommendations (9.1, 9.2, 9.3 and 9.4), particularly the harmonisation of approaches to conducting security checks for access to security sensitive ammonium nitrate. DAFF is also of the view that state/territory governments should not add any additional chemicals to the current security sensitive ammonium nitrate regulations.

3. COMMENTS ON MINOR USE

The problem

Minor crops are those which do not require large volumes of chemicals (insecticide, herbicide, fungicide) to protect them against pests, diseases, weeds and insects. This is because they are grown on a smaller acreage (they are usually horticultural crops), as opposed to broadacre crops like wheat or cotton. They are not necessarily confined to small or niche market crops and can include agricultural produce for which there is a large market, such as onions and carrots.

Manufacturers are reluctant to register products for use on minor crops (known as minor use), or to include minor uses on the labels of chemical products already registered. This is mainly because the cost of generating the additional data required is likely to outweigh the commercial benefit. Manufacturers also claim that they are reluctant to register products for minor uses because of concerns about their potential liability for product efficacy and crop damage. This is discussed in more detail in the section 'Addressing the Problem' below.

Whilst the discussion below focuses mainly on minor crop industries, it is noted that minor use is also an issue for smaller livestock industries such as aquaculture and goats.

Options Available to Producers of Minor Crops

Producers of minor crops currently have a number of options available to them

- attempt to control pests without the use of chemical products
- apply to the APVMA for a permit to use a registered product in a way which is not included on the label (that is, to use it off-label)
- encourage chemical manufacturers to include minor uses on the labels of products which are already registered for use on the same pest on a different crop
- use chemical products contrary to the label instructions, which is illegal in almost all jurisdictions
- only grow crops for which a registered product is available.

The first option is not economically feasible on a commercial scale because non-chemical pest control activities, such as weeding and ploughing, tend to be labour intensive and, therefore, costly. Also, they may have limited application in that they may not control insect pests. Further, attempting to control pests without the use of chemical products may result in crop damage or crop failure and loss of markets that require pest free, high quality produce. Although the organics industry tries to do this, it still requires registered or permitted pesticides to be available, even if they are generally less efficacious than the conventional farming.

The second and third options require investment in providing residue, efficacy and crop safety data. However, many of Australia's minor and emerging agricultural industries are not able to generate sufficient funds to invest in the research needed to generate this data and, because individual farmers are not able to capture the benefits of providing data, there is little incentive to do so. Also, users can be discouraged from applying for permits because it takes time for them to be issued, they are time limited and often include conditions such as a requirement to generate data. With regard to including minor uses on labels, as noted above, chemical manufacturers are reluctant to invest in providing the necessary data because of the limited returns expected.

As a result, producers of minor crops have an economic incentive to pursue the remaining two options – use chemical products contrary to the label instructions (off-label) particularly since the penalties for infringement are usually not sufficient to act as a deterrent or to grow only crops for which registered products are available.

Impacts of Using Chemical Products Off- Label

The product label includes instructions for use to ensure that users are able to meet market access requirements while addressing any risks to human health and the environment. These directions are the result of a thorough risk assessment by qualified scientists at the APVMA. However, when a product is used off-label, the user, and not the APVMA, undertakes the risk assessment. This may compromise the risk management objectives of the NRS and, therefore, result in negative health, environmental and trade externalities. There is also a concern that minor use contributes to the resistance building up in pest populations due to lack of direction given by manufacturers for the specific use pattern required.

Negative health externalities can occur because of the potential impacts on worker safety. Many minor use cropping industries have a relatively large workforce which is required to undertake manual labour. As a result, these workers face an increased risk of exposure to pesticides than those in other occupations. Other health effects of using chemicals off-label include the potential for consumer exposure to residues since the vast majority of minor crops are fruits and vegetables which make up a large and important part of the Australian diet and are often eaten raw. There is also the potential for the general public to be exposed to chemical products as expanding population centres gradually encroach upon primary production areas. With regard to livestock/aquaculture production, negative health externalities can arise because of the potential for consumer exposure to residues of antibiotics used to treat animals (including aquatic animals). This can also have negative trade impacts.

Negative environmental externalities can occur because minor crops are generally grown in rural and peri-urban areas and, therefore, have the potential to affect native flora and fauna. In addition, the use of pesticides of-label can result in them getting into waterways.

Negative trade externalities can occur because of the loss of markets which require pest free produce and when chemical residues in a particular crop breach the maximum allowable limit – known as maximum residue limits (MRLs). When

pesticides are used in crops for which they are not approved, there is no MRL and, therefore any pesticide residue detection is considered to be a breach – although the inclusion of a default MRL would assist in this regard.

Whilst MRLs are nominally concerned with domestic food safety, they are becoming increasingly important as market access issues, particularly where differences exist between Australian MRLs and those of importing countries. In addition, because major trading partners are increasing their level of residue scrutiny and the detection technology is becoming more sensitive, there is potential for the level of violations reported to increase.

Although it is difficult to quantify the negative health and environmental externalities, some limited data on the trade impacts is available. An analysis undertaken for Horticulture Australia Limited of current residue monitoring programs both within Australia and overseas has found that domestic violations appear to be at a level of between 3% and 5%, with violations occurring from both off-label use (no MRL) and exceedance of current domestic MRLs. In terms of Australian export performance, MRL violations have been reported to DAFF for over 20 commodities from a range of countries in Asia, North America and Europe over the last 10 or so years (see table below). A large number of these products are minor use crops for which there is a limited range or no registered product available. More recently there have been problems with MRL compliance reported for the following minor crops: blueberries, celeriac and fennel into Japan; cherries into Ireland; and parasite treatments in goat meat. Given the increasing focus on MRLs as potential trade barriers it can be expected that as the level of scrutiny increases the level of violations are likely to increase also.

Violations reported to DAFF 1994-1999

Country	Commodity
Brunei	Broccoli, garlic, mandarin & strawberry
Canada	Pears
Hong Kong	Lettuce, spinach & salad mixes
Malaysia	Oranges, mangoes, celery, grapes, plums, tomatoes, peas, mandarins and capsicums
Singapore	Lettuce - Cos, Frisee & romaine

If there is one more violation in lettuce to Japan, 100% of Australian lettuce will require residue testing. The costs of these tests will be borne by the importer who will probably pass this cost onto the producer. More generally, produce in which residue violations have been detected is usually rejected from the market and destroyed unless the shelf-life allows it to be sent to another country. In this case, any costs are borne by the exporter and, ultimately, on to the grower.

Such incidents can undermine market confidence in the safety and quality of produce both domestically and internationally. Given that fruit and vegetable production in Australia in 2007 totalled $5,485 million (although not all were minor crops), this could have a significant effect on the Australian economy, particularly in rural areas which are heavily dependent upon the agricultural sector for income and employment.

Residue detections in international markets can also create negative perceptions about Australia's reliability as a market source and, with exports of fresh and transformed fruit, nuts and vegetables totalling $1,184 million in 2006/077, this could have a significant economic impact. Importantly, these impacts can go beyond the affected crops and may result in importing countries imposing more stringent requirements on primary production sectors where it is not warranted.

Impacts of Growing Only Crops for Which a Registered pesticide is Available

This option can have a negative impact on the resilience of rural/regional economies and, in turn, the Australian economy as a whole. The ability to grow a diverse range of crops provides greater economic stability in that it can minimise the adverse effects of events such as pest incursions, water shortages, drought and climate change. In addition, productivity, flexibility and land use efficiency are maximised because growing a diverse range of crops allows producers to grow those which are best suited to the particular soil type.

Addressing the Problem

Given the market failure associated with data generation, the negative externalities associated with pesticides being used off-label and the potential economic impact of primary producers growing only crops for which a registered product is available, there is an argument for government intervention so that minor crop producers can access the pesticide control options they need to be economically viable. Assistance could be provided in the following ways

- reduce the cost of assessments for minor uses
- enforce only the risk management instructions on the label
- undertake low risk crop extrapolations
- limit the liability of manufacturers for minor uses
- improved industry co-ordination
- provide funding towards the research needed to generate data.

The PC Report proposes that the assessment process by the APVMA could be made more cost effective and that the assessment requirements could be reduced where there is a strong case that the minor use results in a lower level of risk. It is noted that the Minor Use Liaison Office (MULO) is working with the APVMA to register existing minor use permits without additional costs to manufacturers and that the cost of applying for a minor use permit is already much lower than the cost of full registration. With regard to the assessment requirements, the APVMA already reduces requirements when the risks are low. However, as noted earlier, the risks associated with minor crops may not always be low because of the importance of horticultural produce in our diet.

Enforcing only the risk management instructions on the label is proposed in the discussion of recommendation 4.6 above. This would assist minor crop producers in that permits would no longer be needed for uses such as on a different pest on the same crop because this is related to product efficacy rather than risk management. Similarly, undertaking low risk extrapolations between/within crop groups so that a

registered product could be used on a wider range of crops, would reduce the need for permits.

Limiting the manufacturer's liability for product efficacy and crop damage resulting from minor uses has been proposed as a way of encouraging them to register these uses. Manufacturers claim they are reluctant to support the issuing of minor use permits because of concerns they may be sued for lack of efficacy or for crop damage, even if the product has been manufactured properly and used in accordance with the permit. The nub of their concern appears to be the cost of insurance. Because minor crops are typically grown on a small acreage, the profit from product sales on a per hectare basis is very small, ranging from $5 – $80/hectare. However, damage/efficacy claims could be high because many minor crops are high value (> $100k/hectare) and it can take a number of years for them to be established - for example, it takes several years for fruit and nut trees to become productive.

PSIC has considered a proposal to limit the liability of manufacturers for efficacy and crop safety by transferring liability to the user. The proposal was rejected on the basis that this would not necessarily encourage manufacturers to include more uses on product labels. However, limiting manufacturer liability might be more acceptable if, in return, chemical companies were to provide a guarantee that they would include minor uses on product labels. Otherwise, users would have to bear the cost of any crop damage or loss, whilst manufacturers would reap the benefits of increased product sales without being liable for damage.

It is noted that, in countries such as the UK and Canada, users of chemical products on minor crops have been accepting liability for crop damage and product efficacy for some time by signing a disclaimer. In Australia, this would be contrary to the Trade Practices Act which does not allow companies to limit their liability. Therefore, unless an exemption could be made, this avenue would not be available.

With regard to improved industry co-ordination, government assistance is being provided through organisations such as MULO and Horticulture Australia Limited, to make more chemicals available for minor uses. This is being done by sharing information and prioritising research so that the benefits of the limited funding resources of these industries can be maximised. However, it can be difficult for those minor crops which do not have peak industry bodies to represent them, to participate in these industry co-ordination initiatives. Further, the future of MULO is uncertain, at this stage, because it was established by the APVMA and DAFF each dedicating an officer for a period of only twelve months**.**

The provision of government funding for the research needed for data generation would not only help to reduce the negative health, environmental and trade externalities but would also produce positive externalities. For instance, there would be spillover effects through the transfer of knowledge and skills and the level of R&D would be higher than if provision was left to the market because of the limited returns on investment noted earlier.

The Australian Government already recognises that individual farmers cannot capture the benefits of R&D and provides dollar for dollar matching funding for rural R&D through R&D corporations (RDC). However, it can be argued that, unlike producers

of broad acre crops who have ready (legal) access to most of their chemical control options, producers of minor and specialty crops need additional assistance. Even with the availability of matching Government funding, a large number of minor crop industries do not have a sufficiently large economic base to fund their own RDC or to be part of another RDC. Further, those which are large enough to be able to access the research services provided by RDCs such as the Rural Industries Research and Development Corporation (RIRDC) and Horticulture Australia Limited (HAL) may still have difficulty in receiving funds since RDCs have limited budgets and do not necessarily see research for minor use as a sufficiently high research priority when compared to other research investments.

If Government funding was to be made available specifically for minor use, it could be provided via RIRDC and HAL. However, as noted above, not all minor crop industries are represented by these RDCs. Therefore, a better option may be to provide funding to MULO so that all minor crop industries can benefit.