



22 July 2020

To:
Agricultural and Veterinary Chemicals First Principles Review
Department of Agriculture, Water and the Environment
GPO Box 858
Canberra ACT 2601

Via: on-line lodgement process

RE: Issues paper “Review of the agvet chemicals regulatory system - Future reform opportunities”

To Whom It May Concern,

I write in response to the first principles review of the regulatory framework for agricultural and veterinary (agvet) chemicals.

1. Organisations involved in this submission

This submission is presented on behalf of the following organisations:

Grain Trade Australia (GTA)

Grain Trade Australia (GTA) is a national association and is the focal point for the commercial grains industry within Australia. The role of GTA is to provide a framework across Industry to facilitate and promote the trade of grain. GTA facilitates trade and works to provide an efficient, equitable and open trading environment by providing leadership, advocacy and commercial support services to the Australian grain value chain. GTA Members are responsible for over 95% of all grain storage and freight movements made each year in Australia. Over 95% of the grain contracts executed in Australia each year refer to GTA Grain Trading Standards and/or Trade Rules.

GTA has established the Australian Grains Industry Code of Practice. All GTA Members are required to adhere to the Code of Practice. GTA Members are drawn from all sectors of the grain value chain from production to domestic end users and exporters. GTA has over 260 organisations as Members. Their businesses range from regional family businesses to large national and international trading/storage and handling companies who are involved in grain trading activities, grain storage, processing grain for human consumption and stock feed milling. A list of GTA Members is attached.

The National Working Party on Grain Protection (NWPGP)

The NWPGP:

- Is the industry body responsible for providing management and leadership to industry in the areas of post-harvest storage, chemical use, market requirements and chemical regulations.
- Is facilitated by Grain Trade Australia.
- Has members across the entire grain supply chain.
- Hosts an annual forum providing participants with the latest research and developments, in the area of post-harvest storage and hygiene, chemical usage and outturn tolerances, international and domestic market requirements, and regulations.
- Co-ordinates and provides government with industry views on chemicals in use on grain and associated products.
- For further details, refer to <http://www.graintrade.org.au/nwpgp>

Within that context, GTA and the NWPGP provides the following submission in relation to the review of the agvet chemicals regulatory system in Australia as it relates to grain only.

2. General

Focus of Review

In this submission, comments are mainly focussed on the agvet chemical legislation and the impact of that regulation on the international trade of Australian grain, however comments in general equally apply to grain traded domestically within Australia.

Given the significant level of use of chemicals by the Australian farming sector, it is understood the issues paper uses language referring largely to the “Australian farmer”. It should be recognised that agvet chemicals are used by stakeholders all along the grain supply chain, post the farm-gate.

Why agvet chemicals need to be regulated p3

GTA/NWPGP generally agrees with the principles outlined in the issues paper in this section. Increasingly markets, either via government regulations or through commercial contracts, are placing greater scrutiny on the residue status of imports of Australian grain. Past experience has shown that the Australian regulatory system is well regarded internationally, including the application of that system by all stakeholders along the Australian grain supply chain. Any review and resulting changes to the agvet chemical legislation must not compromise that reputation, but enhance and where possible assist industry to build on it.

In general, markets either by regulations or customer contracts, do not distinguish a difference in chemicals due to their risk profile. The exception is where an overseas regulator lists chemicals where an MRL is not required. The existing regulatory system in Australia, and overseas, deals with those chemicals which are in general not used by the grain industry and therefore not of significant concern in this submission. The regulations covering those chemicals should not change as a consequence of this review.

Hence a potential change due to re-directing resources from chemicals with a lower risk profile “i.e., due to lack of resources” of the system must not occur unless the same rigour and standards can be implemented. Further discussion on this topic occurs later in this response.

International Context p4

A “*lack of access to chemicals that are available to farmers in other countries*” does on occasions put Australian farmers at a disadvantage. Any change to chemical access made under this review process must not compromise the standards currently employed in relation to chemical regulation and use in Australia. It should be possible to reform the current system to incentivise industry to propose new products for registration

without compromising the integrity of the process or reputation of the national regulator and the system itself.

Where possible, the existing system should be simplified to ensure that regulations such as Control of Use are nationally applied, are transparent and modernised. Existing differences across jurisdictions in Control of Use, training of users, access to chemicals etc. not only leads to confusion among industry but does not support the approach of the industry of “one regulation for all” and compliance with good manufacturing practice/Quality Assurance systems etc. Further discussion on this topic occurs later in this response.

3. A Proposed Vision for the System p4

We note the proposed vision statement that the panel is inclined towards is *“An Australian regulatory system for agvet chemicals that provides all Australian primary producers and veterinarians with timely access to a similar range of approved agvet chemicals to their overseas competitors, while preserving human, animal, plant, and environmental health.”*

While this vision and the measures to achieve that vision (outlined as dot points) are supported in general, a key issue for the grain industry is the reliance on exports for over 60% of Australian grain production. Hence market access is a key element of the current and any future Australian chemical regulatory system. Given the importance of continued market access, taking into account the range of overseas regulations and how they are set, maintaining market access should be specifically referred to in the vision and/or as an added dot point in the underlying “measures to achieve that vision”.

Additionally, the proposed vision states Australia needs access to *“a similar range of chemicals to those overseas”*. This could be interpreted as Australia relying on overseas regulators to lead our agvet chemical regulatory system and hence chemical availability. This should not occur for several reasons including:

- As has occurred recently, in some instances Australia may desire or have access to chemicals before our overseas counterparts.
- The Australian agvet regulatory system should maintain its reputation and be seen to be independent (not a part of/beholding to) overseas regulators and their decisions.
- The Australian agvet system should consider overseas systems and continue to refine etc. based on those decisions made overseas, as it currently does. It should not be “dictated to” by those overseas systems.
- Australia is unique in terms of factors around chemical use such as environment and pest status. Chemical availability in Australia should be decided on uniquely Australian factors and not because a particular chemical is used overseas. Commercial forces will dictate the availability of a chemical in Australia (i.e., whether a chemical registrant develops a suitable data package for registration).

Hence the statement should reflect “access to at a minimum a similar range of chemicals to those overseas” or words to that effect.

The vision implies the proposal of the Panel to only implement regulations for *“Australian primary producers and veterinarians”* will be accepted. That is, by implication, the potential recommendation of ceasing relevant regulations of uses of chemicals in Australia by other stakeholders (i.e., household use) will be adopted. This is not supported by GTA/NWPGP. To maintain Australia’s reputation, access to chemicals used by all Australian users, whether commercial or private, should be regulated. Approaches to manage the differences in risk profile through a revised regulatory process can be managed separately. Further discussion on this occurs later in this response.

4. State of the System

Consumer market expectations and authenticity p7

The issues paper states “...*If these trends continue, with agvet chemicals use declining in favour of non-chemical, or reduced chemical pest management solutions, the regulatory system may be expected to consider integrated and non-chemical pest management solutions as part of its approval process.*”

Before any such changes are implemented or even considered, industry must be fully consulted. There are a range of measures industry currently adopts and intends to adopt over time to address these matters. Additionally, other sectors of government are pursuing these matters with industry (e.g., traceability for key agricultural industries such as grain). While development and adoption of these issues are of interest to the APVMA, they are not key activities that should be of primary focus for an agvet chemical regulator.

Social Licence p8

The issues paper states “...*the growing community concern over agvet chemicals is likely to impact the use of these chemicals in the future—the panel is interested in what mechanisms are needed to build a regulatory system that responds sensitively to these community concerns, and maintains community trust in the use of agvet chemicals*”.

Having a regulatory system that is based on science, is transparent, open and adaptable is key to continuing access to chemicals for the industry. This system is also required to ensure the food supply continues to be safe. Any potential changes as a consequence of community concerns, or indeed farmer concerns with a lack of chemicals, should not jeopardise food safety nor the fundamentals of the regulatory system that underpins food safety. While good communication exists between the APVMA and some sectors of industry such as grain, further communication pathways are encouraged in order to develop appropriate messages to the broader community on all aspects of Australia’s regulatory system and how industries such as grain manage their responsibility. Further discussion on this topic is included later in this response.

Farm Practices p10

This section and many other sections of the issues paper, focuses on the originator of the commodity, in general being the grower/on-farm. There are many other elements of the grain supply chain that also use chemicals and are directly impacted by the current and any potential changes to chemical regulations. This should be reflected in any future strategies relating to the agvet chemical review in Australia.

Electronic (smart) labelling p10

It is recognised that technology in relation to a range of chemical related issues is evolving rapidly. Smart labelling is one area where improvements to transparency of chemical use can be made. There are many other areas that would also assist to address consumer expectations on responsible chemical use, such as a traceability system linking chemical sales, usage by crop, remaining chemicals supplies, potential residues arising on produce delivered to market etc. As stated previously, some of these matters are directly related to APVMA activities and some are considered to be indirectly associated. There needs to be further consideration by all relevant stakeholders on developments in this area and agreement on the role of the APVMA before any such changes to arrangements are made.

Other Future Trends to consider p11

As stated, increased transparency of information will potentially assist in understanding chemical use and therefore addressing to some degree community concerns as users of that food.

Users of chemicals should not be forgotten in this discussion. With changing market requirements, growers need to continually manage not only their commercial operations but also assist marketers/traders to manage grain supply to customers as per regulations. The interaction of different cropping systems, chemicals and impacts of environment on the fate of residues and eventual residues in the harvested crop is becoming more complex.

Greater awareness and transparency of the impact of using chemicals on residues in the grain produced and ultimately consumed is required. APVMA has a role to liaise with industry on greater transparency of information available for grower use, recognising commercial in confidence aspects.

5. Core Objectives of the future System p11

As previously stated in relation to the Vision, maintenance of market access in relation to chemical availability and use is a key driver of the Australian grain industry. This not only relates to chemical use to manage pests, but also to produce a quality product that meets customer requirements, economically.

The issues paper states the following *“The panel is of the view that the purpose of the agvet chemicals regulatory system is to achieve 2 primary outcomes: to protect the health and safety of people, animals, plants and the environment; and to provide users with access to safe chemicals.”*

While that statement is agreed, if that is not done in a clear, scientific and consistent manner, and chemicals available are not able to be used in a commercial operation, then the system will fail and agriculture in general will not be able to commercially sustain a domestic or export industry.

The **proposed primary purpose statement** details *“...It does this by preventing or managing unintended adverse consequences from exposure to agvet chemicals in food, the environment, and the workplace; and by ensuring that suitable pest management solutions are available to safely control the pests and diseases of plants, animals, and places, that threaten the health and safety of people, animals, plants and the environment.”*

This statement does not take into account commercial operations on farm and other reasons for using chemicals. That is, chemicals are not only used to control pests that *“threaten the health and safety of people, animals, plants and the environment”*. Chemicals may also be used to profitably produce grain and also to manage pests that are required to be managed to levels as required by Australian or overseas government quarantine laws or as specified in customer contracts. Thus trade impacts, not just relating to chemical residues are of primary importance when reviewing and setting chemical regulations.

For the above reasons, the proposed hierarchy of objectives with “to protect trade” as a secondary objective does not place trade at a sufficiently important level. As support for that statement, the panel considers “compliance with regulations” a high priority, yet several sections of the issues paper outline possible alternative “looser requirements” to the current system.

6. Principles to underpin the design of the system p14

All the principles as listed are supported to varying degrees, however each agricultural industry has differing priorities on each, noting priorities are not listed in the issues paper.

The principle of *“consistency—there should be one coherent national system, with consistency in control of use and any differences amongst jurisdictions should be required to be justified publicly”* is strongly supported. The current differences in State/Territory jurisdictions in relation to Control of Use, and other matters, no matter the reasoning, causes significant confusion in industry and potentially undermines the scientific basis of chemical regulations developed and implemented by the APVMA.

GTA/NWPGP strongly encourages changes to the current system so that any future system does not have differences in control of use - with all measures equal across Australian States and Territories. That is, GTA/NWPGP considers there are no significantly justifiable reasons from a regulatory viewpoint to have differing control of use regulations where the same (or different) grower or chemical user may be operating across State/Territory boundaries with different rules. That system is not only inefficient but also undermines the validity of the processes the current regulator the APVMA undertakes in developing and legislating label directions and approving chemical use. Further discussion on this topic is included later in this response.

7. Risk-based versus hazard-based system p15

The issues paper clearly outlines the benefits of the existing approach to chemical assessment taken by the regulator, being the risk-based system. Those benefits as listed in the issues paper will not be repeated in this submission, but are fully supported.

GTA/NWPGP fully supports this risk-based approach continuing. As stated previously, the grain industry relies on exporting to a number of overseas markets, mostly adopting a similar approach to the Australian regulatory system. Where a hazard-based approach is adopted, despite a lack of impacts on issues such as human or animal health, the restrictive MRLs pose significant market access issues for Australian grain exports.

GTA/NWPGP fully supports Australia continuing this risk-based approach, which is recognised and adopted by many of the leading regulators in many countries, including at Codex. The approach in Australia is underpinned by label directions to manage any risks. Without such an approach, industry would question the need for many of the label directions currently listed for products, exposing the industry (and community in general) to practices that cannot be fully supported that may ultimately lead to food safety issues.

8. Responsibility for aspects of the system p19

As outlined in the issues paper, the governance arrangements for agvet chemicals in Australia is complex. As noted in the issues paper *“The panel is inclined to seek a governance arrangement that: provides clearer leadership for the regulatory system overall; identifies the different roles of Commonwealth and state and territory governments; and, consistent with the concept of shared responsibility (section 2.4), gives more weight to industry and user responsibilities in the future.”* GTA/NWPGP in general supports that approach.

GTA/NWPGP also fully supports *“The panel has a strong view that there is little justification for considering any changes to the current approach of a single national regulator for the supply of agvet chemicals.”*

GTA/NWPGP has no preference for a specific operational model of the options outlined for the national regulator, however any model adopted:

- Must not remove its scientific and regulatory roles, including any roles related to approving chemical use such as label directions; and
- Should not involve creation of further steps in the decision making process (e.g., require another government “agency”) that may delay or make inefficient that decision making process; and
- Must not compromise the science based approach of the APVMA; and
- Must not compromise the independence from “Government, industry or community” of the APVMA nor its decision making process (i.e., be overly influenced by any one stakeholder over another, including any overseas regulator); and
- Should enable regulatory reform to occur within the principles as agreed (e.g., cost and efficiency); and
- Should not utilise existing APVMA resources on other additional activities unless adequate resources are provided to adequately manage those existing activities; and
- Should enable more efficient communication pathways with government, industry and the community; and
- Should address current industry concerns where outdated information may exist on a State based regulator website; and
- Should address the current complexity of interaction by the many agencies responsible for the Australian chemical system.

9. Control of Use p23

It is recognised “*efforts to nationally harmonise control of use across all states and territories has been an ongoing challenge for the agvet chemicals regulatory system since it became national*”. Nevertheless GTA/NWPGP supports national harmonisation of access to appropriate chemicals, consistent rules on chemical use and a consistent compliance and enforcement regime for all users and State/Territory regulators.

Without harmonisation, inefficiencies and confusion of regulations that currently apply will remain, leading to the potential for non-compliance by industry for varying reasons. This could jeopardise Australia’s reputation, leading to a number of consequences such as a loss of vital chemistry or loss of reputation and market.

GTA/NWPGP supports harmonisation as soon as possible of many of the measures identified in the issues paper that are still yet to be fully addressed despite several years of work, being:

- *“Arrangements for licensing fee-for-service users (excluding operators on their own land).*
- *Training and competency assessments for users of certain highly hazardous chemical products.*
- *Record keeping requirements for agricultural chemical use.*
- *Off-label use of agvet chemicals.*
- *National coordination of domestic produce residue monitoring”.*

Of the potential approaches to reform the agvet chemical regulations in this area, GTA/NWPGP supports option 1, “*Expanded applied law model*” provided that the allowance for each jurisdiction to decide whether to apply the legislation can be addressed and in essence, not permitted within reason (i.e., unless vital). Support for this option is as per the wording in the issues paper, but significantly “*This would provide certainty, efficiency and reduce regulatory costs for chemical registration holders, Australian farmers and other chemical users*”.

Option 2 “*Commonwealth exercising its full constitutional reach*” may also be suitable provided mechanisms could be developed to ensure that the “gaps” identified would not lead to any significant differences in legislation applied by the States/Territories (as currently occurs).

For option 3 “*Re-invigorating the existing Intergovernmental Agreement (IGA) on control of use*” the justifications as listed in the issues paper have merit. However there appears to be several issues to be overcome with this model, including resulting in operational increases and the inability to reach agreement on this IGA.

To re-iterate, GTA/NWPGP does not support current control of use failings and strongly encourages the panel to adopt a model of national control of use legislation. Different controls of use across States weakens the national regulatory system and in effect compromises the integrity of the Australian system.

That national approach should also extend to label directions, compliance, reporting and a range of other information on chemical use across jurisdictions. For example, as label directions alter, there are instances where information on a website of one jurisdiction remains outdated and not updated. This causes confusion within industry and undermines the national regulator role of controlling the registration of a chemical.

In summary, each model has elements of merit and GTA/NWPGP is not fully committed to option 1, but requests further consideration by the panel to adopt an option that delivers the reforms as listed without each State/Territory jurisdiction embarking on a significant deviation through its own legislation.

The current proposal to reform agvet legislation creates an opportunity to harmonise this control of use legislation and the full benefits of regulatory reform will be lost if this goal is not achieved.

10. Shared Responsibility between government and industry p29

GTA/NWPGP supports the concept of shared responsibility as outlined in the issues paper. Specifically, training in the supply of chemicals (and users of chemicals) should be required and be consistent nationally. This often is the first and sometimes only point of contact for a purchaser of a chemical prior to use. While advocacy efforts of industry are increasing, there is a gap in the knowledge of chemical suppliers on the impacts of chemical use on market access.

A shared approach to training and/or advocacy between industry and government should be explored to ensure a minimum level of knowledge is required when supplying chemicals. Any implementation should follow the principles as previously stated as being consistent across State and Territory jurisdictions.

11. Duty of Care p33 & compliance and enforcement p35

Regarding duty of care of chemical users, there is an expectation that the regulator only registers a chemical for use, that amongst other things, when used according to label directions does not pose a risk to the safety of human and animal health and welfare, the environment or Australia's domestic or international trade. If a chemical user does not comply with label directions, these expectations may not be met and the regulator should have appropriate mechanisms in place to follow-up such behaviour.

GTA/NWPGP believes that "regulations should be enforceable". Without an adequate ability to enforce regulations, benefits of any regulatory reform and possible improved confidence in the system may not be fully achieved. This enforcement role should include rules to be applied and how that process is managed nationally. For example, at present, there appears to be inconsistent rules followed during trace-back of residue issues arising in commodities exported. In recent discussions with States/Territories on "what rules would apply", varying responses were received on which MRL would be applied (i.e., FSANZ, APVMA, the higher of the two). While the grain industry does not wish to implement stricter rules than present, that are unworkable from a practical viewpoint or add no advantage to food safety etc., the different approaches by jurisdictions in this example do not assist industry understanding of the rules, their obligations and thus outcomes for industry and the community in general. There are other examples where improvements to the regulatory system can be made.

As part of these enforcement provisions, the regulator and industry should develop a communication and advocacy program to users of chemicals (and other relevant sectors of the supply chain) commensurate with the risk of that violation of label directions. Low risk consequences may simply require a discussion and education on label directions. A high risk event (e.g., deliberate mis-use of a chemical where no registered use on the label exists) may require a different approach.

In many instances, a chemical user may apply a chemical according to label directions, yet because of differing market MRLs, that grain may not be suitable to supply to a particular market. Because of supply chain commingling and other contractual issues, in most instances the chemical user (e.g., grower) does not know the market destination when applying those chemicals. In this instance the grower has followed their duty of care obligations and should not be penalised for supplying grain "that does not meet a particular market requirement". Hence further industry/government discussion on the approach to developing duty of care obligations in any future regulations is required due to the complexity of the issue.

At present, there is no consistency in managing and reporting adverse chemical residues being detected, nor used incorrectly. In many instances there are no regulatory incentives for reporting of violations by industry. While industry has implemented some advocacy efforts in this regard, further regulatory support is required to enhance the current system. Additionally, there is a lack of adequacy of the current regulations to manage inappropriate recommendations due to those sectors of industry making those recommendations using "subtly worded communication that meets the intent of label directions". Targeted monitoring and enforcement activities in these instances should be able to be implemented to curb such behaviour and provide greater confidence in the enforceability of the regulations.

Again, details of such a revised approach under the reform agenda need to be thoroughly considered jointly by government and industry. Adoption of a system that highlights issues unnecessarily (i.e. low risk incidents) places Australia's reputation and market access at risk.

GTA/NWPGP supports the views of the panel that more resources need to be targeted to detection and investigation activities, with an agreed strategy on education versus legal sanction response for the range of incidents that may arise.

12. Chemicals to be Regulated p39

GTA/NWPGP agrees with the principle identified by the panel that duplication of regulation is not warranted. Additionally that low risk chemicals regulated elsewhere by government should not fall with the scope of the agvet regulations.

However some of the chemicals regulated under Australian Consumer Law (i.e., household products) have the same active ingredient as those used in the broader farming sector. Any change in regulation (i.e., MRL) perception of a chemical by the public has a direct link with these two uses. Hence GTA/NWPGP would not support a differing approach to regulation where a specific chemical is used by both sectors.

Additionally GTA/NWPGP disagrees with the following proposal to exclude from consideration by the agvet chemicals regulator:

- *“Products supplied to the home garden and domestic market”*. Industry when applying chemicals in the main, do not know the final end use for the grain. It may or may not be the domestic market. Additionally many domestic market grain commodities may be processed or exported overseas. Hence regulations relating to agvet chemicals in Australia are required to be complied with. In some instances there is a flow-on effect of a chemical used for home garden use and the wider agricultural sector. In this case, the perception is on the chemical itself, not where it is used. Hence the chemical should be regulated, no matter the use to ensure consumer confidence and that there are no safety risks associated with use of the chemical as per label directions.
- *“Products modifying the effect of another product such as wetters, spray adjuvants and spray markers”*. As these products may alter the ultimate chemical residue in the harvested grain, these products must be regulated in order to understand the risks and resulting chemical residues of applying these products and the chemicals they may be applied with.

13. Regulation of Agricultural and Veterinary Chemicals together p42

GTA/NWPGP has no firm views on this subject. The ultimate decision to keep or separate the functions should ensure:

- A consistent approach to control of use (i.e., storage, training of users, record keeping etc.) be implemented, given in many instances the same stakeholders are involved in these activities.
- Any change does not impact on the ability of the regulator to perform its functions in a cost effective manner.
- Any change does not impede the work of the regulator and does not require additional resources.

14. Gaps in agvet chemical regulation and management p45

GTA/NWPGP agrees with the panel's view that wherever possible state/territory boundaries are no longer included or relevant in most instances when registering chemicals and creating label directions. It should be the responsibility of the registrant to provide the regulator with sufficient details of the applicable usage

patterns based on geography, climate etc. Based on the evaluation of the regulator, appropriate usage directions can then be placed on the label that may or may not include state/territory based directions.

GTA/NWPGP was not aware of the statement included in the issues paper of *“The panel welcomes AGMIN’s decision of 2019 to allow, subject to some restrictions, chemicals that are registered for use in two or more jurisdictions to be used in all jurisdictions for all uses included on the approved label. The panel would like to see jurisdictions give full effect to this change as a matter of urgency, and also recommends wider publicity for this reform.”* As stated previously in this submission, there are various gaps in communication that need to be filled for a range of reasons. This 2019 decision is but one example where benefits for industry would be gained with more effective communication.

There are many outdated labels retained in the Australian regulatory system. That applies to labels under the “PubCris” section and information published on individual state websites. Usage patterns vary over time based on a range of factors including pest pressure, pest resistance, changing farming practices, changing market conditions etc.

The requirement for efficacy to be considered during the registration process should continue. It is the understanding that registrants develop this data in order to show potential users of the product that the stated uses are supported. The review of this data by APVMA provides a degree of legitimacy to the claims added to the label once registered. It is recognised APVMA consideration of this efficacy data is resource intensive. Consideration should be given to refining the review of this data, such as using external experts rather than APVMA staff.

GTA/NWPGP supports the view of the panel that there is *“potential for legal obligation, for registration-holders to review their product label at least once every five years to ensure it contains correct and current information”*. Further discussion with industry on the appropriateness of the 5 year rule and how that consultation and review could occur, given the many stakeholders involved. Additionally, the complexity of a change in label where many registrants have the sample product/labels (e.g., for generic products) will need careful consideration should such a change be approved.

As with the development of crop groups, GTA/NWPGP supports where possible the creation of pest groups in order to improve efficiencies. One note of caution for this approach, as alluded to in the issues paper is the information required to be generated and updated on establishing representative pests in those groups. A further issue to be considered is the changing nature of pests via resistance, requiring continual review of those pest groups, representative pests and ultimately the effectiveness of the chemical against those pests. Significant industry and government interaction is required in order to develop a model on this approach that would not only be effective but would be readily updated over time.

15. Including benefits in assessments p48

GTA/NWPGP has two main concerns with this proposal:

- The ability of the regulator to conduct this assessment with existing resources. As a consequence in the case of not having sufficient or skilled resources, what cost to industry would this incur and therefore provide benefits over that cost.
- How to define each of the stated “benefits” to be considered. Increasingly society is becoming divergent on their views on a range of issues related to chemicals and their use. These views vary over time. The current regulatory system is based on science and thus can be “readily defended”. Criteria such as social benefits are difficult to define especially with changing consumer behaviour over time. While not listed in the factors that the panel is disposed towards including in a benefit assessment (page 49), in some cases it could be expected that submissions may state registration of a chemical is not supported based on social grounds such as views of a sector of society, being at odds with the benefits to the broader agricultural sector of that registration. In this example, the balance between the two sectors will be difficult to manage and the advantages of undertaking this stated benefits test may be outweighed by the complexity and ultimately differing opinions on the benefits of each ruling.

Additionally, as an example, the presence of residues in the environment despite being at levels not considered harmful but present in a wider geographic area such as soil/plants, may be considered as a negative in this benefits proposal by some sectors. This may result in the chemical being not approved or registration removed because of its widespread abundance in the environment. Social “licence and community views” on chemicals should not over-ride or influence decisions of the regulator for approval of a chemical based on sound science.

16. Impact of chemical combinations p50

As stated in the issues paper, there are no set measures used internationally by regulators to assess the impacts of chemical combinations when considering to register a chemical for a particular usage pattern. In the absence of clear and transparent rules, data requirements of regulators etc. introduction of such a system will potentially lead to confusion.

It is noted that data may exist on the known impacts of chemical combinations. Where this is available the registrant should make the regulator aware of this information. Additionally, following registration and use, if the impacts of chemical combinations are known, that information should be provided to the regulator.

To enable such a “voluntary” system to work effectively, thereby reducing resources, the potential for harm to crops and the environment etc. as soon as possible, the regulator should develop a protocol with registrants and industry outlining a process for capture of this information and how it can be managed and passed on. Hence GTA/NWPGP supports option 3 and 4.

GTA/NWPGP could not support option 1 as there are no clear guidelines for what could be termed a “common and well-known group of chemicals”. The importance of chemical combinations varies by chemical, commodity, location, use etc. What is considered important for one user may be different than another. Hence the complexity of the regulator/registrant and industry agreeing will be difficult to achieve any meaningful outcome.

17. Data mining p52

GTA/NWPGP agrees that data mining could be an important initiative to enhance the regulations and efficiency of managing those regulations. However this could only occur where there are no commercial issues such as intellectual property or where valid information is held and would be useful to the regulator. Hence further discussion on the potential for this recommendation to be implemented before any final decision is made should occur. As noted by the panel there are a range of issues to be managed and considered, including protecting intellectual property and privacy.

One option stated in the paper is for agvet chemical users to mandatorily report chemical usage data to the regulator. GTA/NWPGP does not agree with this proposal for a number of reasons:

- The value of that data versus the cost of generating the data and ensuring it is accurate, completed, able to be audited etc.
- The lack of ability of the regulator to enforce that requirement. If enforced, the expected cost of enforcement using current systems would be extensive.
- In general the use of a chemical does not reflect the safety of the ultimate commodity to which that the chemical was applied. There are many activities in the supply chain that “dilute the residues arising following the use of a particular chemical at one point in time”. From this aspect there would be no value in generating that data of chemical use by commodity.
- Industry systems are either available or being generated to automatically capture chemical use on farm. Discussions have occurred with government and industry on development of traceability programs to show the “fate of residues of chemicals applied” from the point of application to the ultimate end-user. Various drivers for this change and information exist and requirements are rapidly

changing in this area. Given the rapid changes occurring, a greater focus should be on all sectors of the chemical supply chain (regulator, other government department, chemical users, other relevant supply chain stakeholders) engaging to develop systems that capture the required information for the purposes required – such as market access. Once such systems are developed there may be benefits for reporting to a regulator.

- Domestic and overseas customers are increasingly seeking information on the food safety aspects of grain. However, this is not uniform by market, nor by commodity or location where the crop is grown/marketed. As requirements evolve industry will develop appropriate mechanisms to maintain that market access. Implementation of blanket systems for all commodities and all users is not required at this point in time.
- As stated previously, Australian grain growers have a good reputation for compliance with label directions. However it is recognised there are instances where this does not occur. The benefits of the regulator enhancing its monitoring, auditing and compliance powers in this regard would significantly outweigh the cost of developing mechanisms for mandatory reporting of chemical use by all chemical users.

18. Monitoring chemicals in produce and the environment p55

Testing per se or increased residue testing will have little benefit or impact on increasing the public's confidence in the regulatory system. Rather, unless there are clear messages around what is detected and the meaning of in many cases "expected residues that will be found", the opposite will occur and the somewhat "breadth of residues found" would possibly lead the community to a lack of faith in the regulatory system.

Residues are expected in any system where chemicals are used. The fate of those residues in the environment, water and food are the keys to ensuring which permitted chemicals are being used correctly as per label directions. Monitoring of residues in grain and ultimately food is key to preserving the grain industry reputation in Australia to show that a high level of compliance with label directions occurs. It is understood the Australian Total Diet Study conducted every two years shows good compliance with regulatory requirements and a relative lack of chemical residues in food. The potential exists to expand this survey or at least utilise and publicise results better to inform the general public of the general safety of chemicals being used to produce their food.

GTA/NWPGP has no objections to widening the scope of residue testing. To widen the testing to include other areas such as water, the environment etc. would require clear and consistent messages to be provided to the general public regarding the purpose of that testing and the results generated. For example, noting that residues of a particular chemical in the environment may not present any issues from a GLP compliance label viewpoint, food safety or other concern.

For the grain industry, both the National Residue Survey and industry monitor residues in domestic and export grain either via mandatory participation or as required by industry based on market requirements. The National Residue Survey program is a robust program, with a highly recognised and rigorous sampling and testing reputation. However, while the transparency of the information arising from the testing is good (to those in industry that are aware of the program and results), it could be improved through provision in a different form to industry and the wider public in general. It is increasingly apparent more information is being sought by all sectors of industry and overseas markets. Better utilisation of the residue data would assist Australia's marketing efforts and help to sell the message of the safety of Australia's produce.

No single system to manage this testing and communication is applicable to all agricultural commodities. In recent years various government initiatives have attempted to "gather general information on the safety of all sector produce" however these measures have been piecemeal and relatively ineffectual. A nationally co-ordinated strategy by commodity sector, based on a range of issues for that sector (i.e., key chemistry used and or highlighted by market, highest residues in shipments etc.) could be used as a blueprint to develop those strategies.

Testing of shipments for all possible chemicals used and using that information in some communication is extremely costly and commercially sensitive. The competitors of Australia would seek to use any information to their marketing advantage. Again, one strategy does not meet all sector requirements. Consideration is needed on the best strategy to be implemented, taking into account industry systems to manage market compliance (including regulatory compliance). Formal residue testing systems should not be mandatory for all commodity sectors, given the lack of imperative from some markets and the lack of monitoring etc. by some markets. Should such a system be implemented, it must be done nationally for consistency, as State based systems will lead to confusion and potentially biased results depending on the testing process itself.

As previously stated, growers are increasingly seeking information on the use of a chemical and the resulting residue in the produced food. Often there is little relationship given the blending and other factors that occur throughout the supply chain. The complexity of the differing supply chains may lead to further residue dilution, again requiring consideration of the purpose and usefulness of residue testing.

It is agreed that a national approach to sampling and testing should occur for each commodity sector and that this should include testing of domestic produce. Given the robustness and recognition within the grain industry of the National Residue Survey program, this should be the starting point for any refinement or development of a revised testing system.

GTA/NWPGP cannot comment on other non-grain agricultural sectors. Given the nature of each, it may not be feasible nor needed to standardise those sampling, testing and reporting arrangements across all commodity sectors. However given that "Australia Inc. is regarded as a supplier and not individual States or Territories when supplying grain overseas", any arrangements for grain should be applied consistently at a national level.

Additionally a range of influencing factors should also be considered in any review of such a system. This should include standardising sampling programs, standardising methods of analysis where possible, levels of detection used to show "residue free" etc., as these are all factors faced by the industry when exporting into countries with different requirements in this regard. Government should work with industry to identify high risk chemicals and those that through their usage pattern may lead to high risk of contamination in the environment such as waterways.

As stated previously current regulations relating to off-label use of chemicals should be reviewed to further minimise the potential for incorrect residues to arise.

19. Communication and Engagement p60

GTA/NWPGP strongly agrees with the statement in the issues paper *"Failure to manage stakeholder relationships, particularly failing to engage effectively with the broader community, could result in an unnecessary loss of confidence in the continued use of agvet chemicals—with flow-on impacts to agricultural productivity, animal welfare and the environment. This is being seen in a growing number of overseas markets, where misunderstanding and politicisation of the risks of agvet chemicals threatens their continued use and availability.*

With Australia's dependence on agricultural outputs—and a growing (and increasingly affluent) global population to feed and supply with fibre—Australia cannot afford to lose access to safe and effective chemical pest management options. It is important therefore, that industry and government work to effectively communicate and engage with all interested parties".

This failure to manage stakeholder relationships has already been seen in a number of markets where the impacts have not only been loss of key chemistry in an overseas destination market but because of the eventual flow-on effect on MRLs, the loss of use of that chemistry in Australia. Where a market prohibits use of a chemical in many cases the MRL will "eventually decrease to the level of detection/quantification or zero", the timeframe for that change depending on a range of factors. In several cases the loss of that chemistry is not due to legitimate scientific food safety issues but consumer concerns over that chemistry. Note it is recognised that some more toxic chemicals are understandably reviewed and their use prohibited, the grain industry has no concerns with that approach provided the reasons can be scientifically justified.

As stated previously, GTA/NWPGP believes government has a role to assist industry (chemical users, grain traders and chemical registrants etc.) to provide a range of information on chemical use related to the production of food. Key to that is the independent nature of the APVMA and their role in explaining how decisions are made.

A clear example where APVMA (among other key internationally recognised regulators) has assisted to “sell a clear and concise message” is the ongoing community concerns with glyphosate. APVMA advice on the food safety aspects of glyphosate regulation, coupled with industry messages on a range of topics including the need for its use, have assisted in some way to allay community fears of residues on food, in the environment etc. That said, there is room for a more strategic role and interaction of APVMA with industry and while some efforts have proven positive in recent years, further work is required.

This interaction is required not only to assist understanding of Australian consumers and public in general but also those within our overseas markets who place pressure on their own government regulators receiving our grain.

Some of those improved communication mechanisms will need to provide greater transparency over residue data and what residues on food etc. mean from a consumer perspective, as stated previously in this submission. At present, while residue studies are done and reports generated there is in general a lack of transparency and interpretation of that data for use by the general public.

Messages need to be clear in their content and not lead to mis-information or being considered in a “non-appropriate manner”. Communication should support the current regulatory system and marketing effort of the industry, showing a good compliance and record of safe and effective chemical use. Consultation mechanisms need to be both formal and informal depending on the issues. To ensure the appropriate messages and pathways are developed a clear and detailed strategy needs to be developed and GTA/NWPGP and other grain industry sectors would assist in that process if agreed as an outcome from the current review.

The consultation mechanism adopted may need to be in two parts, firstly a general community consultation on chemicals and secondly a more focussed industry consultation on specific issues of relevance to that industry:

- For the former, adoption of regulator/community model mechanisms such as those used in the UK and USA should be explored, provided the stakeholder involvement has clear boundaries and any party does not have undue influence.
- For the latter, more detailed consultation on issues affecting the specific industry, strategies moving forward etc. As a general principle, these consultation sessions as proposed should not be open to the public given the expected undue influence on activities of that group.

For both the above consultation groups, if adopted, the topics to be covered are complex and varied depending on the audience for the consultation and ultimate messages arising. However any such consultation should not compromise the integrity and decision making process of the APVMA in relation to approving and reviewing chemicals. That way, the influence occurring overseas in some jurisdictions of politics and consumer sentiment, where not warranted, can be avoided.

Other key considerations to be explored include the costs of such consultation and who would pay/benefit and the interaction outcomes on the length of time such consultation has on the overall regulation of chemicals.

20. Can the regulatory system be simplified – p65

In terms of the “repack” options to be adopted, GTA/NWPGP has no preference on any option. However it is noted that under option 2, if the pioneer product is cancelled all repacks may be cancelled except where supporting data is held. This may leave the trade exposed where residues are present on the grain through this “legitimate GAP” but the pioneer registrant has withdrawn their product from the market for reasons other than health and safety concerns. In this circumstance the flow-on effect of the legitimate use of a chemical and a subsequent review of the applicable MRLs should not be detrimental to the ongoing use of that chemical.

Regarding efficacy, due to a range of factors, over time, chemicals may become less efficacious. To the understanding of GTA/NWPGP, in general the APVMA does not reconsider label directions over time but leaves that to industry to initiate. Where there are a number of registrants for a particular active, a better co-ordinated system is required to manage any changes to label directions. The current system of “ensuring the main registrants generate data and then change their label” and by “default” the more generic holders will follow (or cancel registration) is too loose and unworkable.

GTA/NWPGP agrees only with the underlined section of the statement outlined in the issues paper of *“that the Australian regulatory system needs to be innovative and open to new approaches that counter this barrier. Being able to accept international decisions on approved agvet chemicals products would allow Australia to become an immediate joint launch market alongside the international reference country, significantly speeding up entry of products into the Australian market, thus providing Australian users with timely access to the same chemical products their competitors have access to”*.

GTA/NWPGP strongly disagrees with the remainder of that statement. Any decisions on registration of a chemical in Australia must be based on a range of current assessment criteria applied, including Australian GAP and trade and market access issues.

GTA/NWPGP understands that trade assessment is unique to Australia when assessing and regulating chemicals. That system has worked well in the past, enabling a range of chemicals to be registered where the impact on trade through use of that chemical can be managed. Conversely, where industry cannot manage those trade risks through use of a wide array of tools and systems, specific chemicals have not been registered until such tools and systems have been developed. That process is vital to continue for an industry such as grain that has a significant export focus.

Hence a chemical approved in an overseas country for use on a commodity should not automatically be approved in Australia. There are many issues with adoption of such an approach, including:

- The underlying process of registration is different (i.e., trade considerations are reviewed in Australia). It is also understood timeframe for registration, costs etc. are vastly different in some countries and adoption may lead to lengthier times and costs for registration in some instances than currently in Australia.
- Strict rules of assessment (and re-assessment) that differ between countries. A flow-on effect may be that a reduced “pool of APVMA experts” are required in Australia. That reduced staffing level and experience may be difficult to increase/train etc. in a timely manner to benefit industry if a range of new chemistry or registration applications are made in Australia. Additionally, should a review of a chemical occur in an overseas jurisdiction that should not necessarily drive a review in Australia. Hence careful consideration of the type of information available from overseas used in the registration/review process here is needed in order to not incur unintended consequences.
- What “regulators overseas are considered comparable to Australia” would be difficult to develop, to ensure sufficient rigour as per APVMA processes are followed and not perceived to be reduced.
- The process of chemical registration would not be seen to be independent, relevant to Australian conditions and possibly be seen to be led by overseas influences.
- Given the different usage patterns, pest profile etc. it would be difficult to manage expectations of industry where for example a decision to ban/not register a chemical for political reasons overseas would unduly influence the Australian registration. Those overseas decisions should not influence the Australian decision making process unless the existing criteria for registration/review in Australia are undertaken.
- Relying on data from overseas would not necessarily benefit the producer to understand the efficacy of a chemical under Australian conditions.
- Without Australian data to support a registration, withdrawal of a chemical overseas (for any reason justified or not) may result in withdrawal here as no “data” would be held.

It is understood that the APVMA have been reviewing their processes and systems and have greatly increased their performance in the last 2 or so years. That reform process needs to continue but not at the cost of “changing the focus of their system as envisaged with the current potential proposal to adopt overseas products from comparable regulators”.

21. Minor/Emergency Use – p89

GTA/NWPGP agrees with the panel’s view of “*supporting the government's actions to address minor use and support Australian growers' access to safe and appropriate chemical products*” and “*greater alignment with international approaches on minor use to identify where international decisions have relevance to Australian growers or expanding export markets*”.

To adopt that approach the resources (used by APVMA to implement this system) should be reviewed to ensure it is appropriate to the benefits the minor use system generates. That is, GTA/NWPGP in general considers additional resources may be warranted to “speed up the decision making”.

However as noted throughout this submission current considerations of the impact on trade and market access need to continue to be included in any decision making process. That is, the ability for a grower to have rapid access to key chemistry to control a specific pest in a minor crop is commended. However if the use of that chemical results in residues on the crop rendering it unsaleable in markets, then the system fails. It is noted in the issues Paper “*issuing a permit the regulator must be satisfied to the same degree of the use of the product in terms of safety, efficacy and trade risks as if the product use was being registered*”.

Additionally, as previously stated, any minor use permit system must be managed and consistent nationally.

22. Chemical Review – p91

GTA/NWPGP supports the concept of “*The panel supports this suggestion and considers it appropriate to focus chemical reviews solely on the specific issues that warrant review rather than requiring the regulator to reassess all aspects of the original approval*”.

In general, some reviews undertaken by the APVMA have been relatively lengthy. In taking a significant timeframe for a review, there is a risk of perception that the regulatory decision is too slow if the review is done on a chemical that may be seen as a safety related issue. A more rapid review would instil greater confidence in the regulator that a decision to review, and thus continue approval or modify/withdraw a chemical in a more timely manner and its use would be seen as a positive by the general public.

In terms of other aspects to be included to drive a review, a change in market requirements (MRL etc.) should not be considered as a driver as that is the role of industry to manage. Hence GTA/NWPGP supports a risk based approach rather than a set timeframe for review that may utilise resources for no significant benefit where there are found to be no “grounds for a review or changes to the outcome”.

23. Use of Technology – smart labelling p92

It is clear that some labels are complex and unfortunately, outdated. The mechanisms for updating labels with minor changes are cumbersome and there does not appear to be a simple and cost effective process for change and updating of all labels held by registrants.

Hence any changes to the method of providing label directions, review of those directions and updating should be explored as a matter of priority to ensure that label directions are as up to date as possible. Confusion in label directions, different label directions for the same product etc. all run the risk of non-compliance with approved use and thus leading to inappropriate residues arising on the commodity. Consistent and clear label directions are a key driver of the regulatory system given that label directions are a significant component of the approval process, with the outcome of use of a chemical as per label directions ensuring that residues are not expected to exceed Australian MRLs.

The current separate mechanism of the “database of registered products by pest/commodity and the label” is unwieldy and cumbersome. It does not readily assist transfer and access of knowledge of the required information for correct chemical use nor uses by pest, commodity etc. Linkage of these two elements with search functions by pest, commodity etc. would greatly assist industry and should be explored.

Additionally, while separate to this topic, sectors of industry are continually frustrated with the inability to determine if a currently registered product is actually used. A clear example is “shelf products” where there is no intention to market the product. Avenues to gain such knowledge should be explored under any regulatory reform to better assist industry in a number of ways such as:

- Determine if alternative chemistry is more suited to be used (for example for IPM, pest resistance management).
- Where changes to market MRLs have occurred and continued use may impact on market access.
- Where a current registration is proposed to be altered (i.e., TAN from APVMA) enabling industry to more adequately to assess trade risks of altering that usage pattern.

Thank you for your consideration of this submission.

Yours sincerely,



Gerard McMullen
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