Inquiry into the Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018

Submitter: Herbicide Consortium

Impacts to forest growers of proposed changes to Agvet legislation

The Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018 (the bill) seeks to amend the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (the Administration Act), the *Agricultural and Veterinary Chemicals Code Act 1994* (the Code Act) and the *Agricultural and Veterinary Chemicals Legislation Amendment Act 2013* (the Amendment Act).

The bill will also repeal the *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014*.

National Registration Scheme

Agvet chemicals are regulated through a cooperative National Registration Scheme (NRS). The NRS is a partnership between the Commonwealth and the states and territories with an agreed division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities up to and including the point of retail sale, is undertaken by the APVMA. The control of Agvet chemical use after supply is the responsibility of individual states and territories.

The NRS is implemented, in part, through the Code Act. The Code Act contains, as a schedule, the Agricultural and Veterinary Chemicals Code (the Agvet Code). The Agvet Code operates in each state, the Northern Territory and each participating territory (the Australian Capital Territory and Norfolk Island) to constitute a single national Agvet Code applying throughout Australia.

The Administration Act and the Code Act, including the Agvet Code and any regulations or legislative instruments made under these laws, are collectively described as Agvet legislation.

The proposed legislative changes aim to improve the effectiveness and efficiency of the national system for regulating agricultural and veterinary (Agvet) chemical products. The changes will:

- **enable the use of new, simpler regulatory processes for low risk chemical products (to simplify the approval of active constituents and labels, and the registration of certain products)**
    - New sections 14C, 14D and 14E provide for a person to apply for the approval of a prescribed active constituent, approval of a prescribed label or registration of a prescribed chemical product as a prescribed approval or registration. These prescribed approvals and registrations represent a new approval or registration process that will be quicker and less costly than the current approval or registration process.
    - The kinds of active constituents and chemical products subject to prescribed approvals and registrations are anticipated to be those that have sufficiently low

associated risk as to warrant reduced supporting information requirements. Examples may include certain:

- applications involving well-characterised chemistry or existing pharmacopoeial active constituents
- products with a history of safe use
- applications with assessments conducted by accredited third party providers.

- For these active constituents and chemical products it is conceivable that no technical information may be required and, as such, this mechanism could support the introduction of a means of self-approval or self-registration, where appropriate. This new process closely mirrors the existing process (including there being no requirement for a preliminary assessment) for prescribed variations where approvals and registrations are varied through a simplified process.

- **provide the Australian Pesticides and Veterinary Medicines Authority (APVMA) and industry with more flexibility to deal with certain types of new information provided when the APVMA is considering an application**
  - The amendment provides for the APVMA to be able to consider the kinds of information that would be prescribed in regulations during the assessment period for an application.

Consortium comments: Forest growers should support the above changes as they will benefit small users (forest industry) by simplifying the regulatory process and make registration and label changes more efficient.

It will be important to know how the APVMA are going to implement these changes, i.e. how they will change their processes.

It would be useful for the APVMA to publish a list of "prescribed" chemicals (or classes of chemicals) that will be subject to the simplified process.

- **provide for extensions to limitation periods and protection periods as an incentive for chemical companies to register certain new uses of chemical products – particularly those uses (minor uses) with insufficient commercial return for chemical companies to normally add to the product label**
  - The existing data protection period is insufficient for some new active constituents or product uses to be brought to market. This is especially true for those actives and uses that are not expected to produce sufficient economic return to offset the cost of approval or registration (including data generation). Some active constituents or uses that are unlikely to be introduced into Australia in a timely fashion under the existing market dynamics may be particularly important to Australia and could include those needed to support agricultural productivity or to control weeds and pests of national significance. The amendments help overcome this barrier.

Consortium Comments: Double-edged sword for growers – provides incentive for chemical companies to develop and register new chemistry that will aid growers and negate the need for minor use permits, but will (likely) keep prices higher for longer because of reduced (no) competition or generics. This change only protects the information generated by chemical

companies and prevents other companies using that data to support their own case. It does not prevent other companies developing similar products and generating their own data.

Would like to see provision for the APVMA to consult with relevant peak industry bodies (users) before setting protection periods, to better gauge industry support for the costs and benefits of the new products.

- **support computerised decision-making by the APVMA**
    - amends the Agvet Code to allow the APVMA to choose to use computerised decision-making as part of its processes, thereby increasing efficiency. For example, computerised decision-making might be used for decisions involving an administrative check of an application where currently all decisions, including those of a largely administrative nature, require an APVMA staff member to turn their minds to the matter at hand.

Consortium Comment: Forest growers should support the above change as it will benefit small users (forest industry) by simplifying the regulatory process.

- **provide for a legislative instrument made by the APVMA to prescribe a scheme in the future that would allow applicants and the APVMA to use accredited third party providers to undertake assessment services**
    - Moving the function of conducting or commissioning data assessments from the APVMA to third-party providers has the potential to:
        - provide applicants with greater flexibility over data assessment timeframes and costs
        - simplify administration processes within the APVMA
        - increase efficiency of application processing
        - open data assessment to greater competition.
    - These measures will allow the APVMA to accredit persons for assessments of information the APVMA receives. The APVMA's legislative instrument will provide community confidence in the assessors of agvet chemical products as it could, for example, specify requirements for experience, insurance, conflict of interest measures and data handling protocols. The instrument could also include requirements for an audit and compliance program. This would help ensure quality and consistency, and safeguard the integrity of the third party assessment process.

Consortium Comment: Forest growers should support the above change as it will benefit small users (forest industry) by simplifying the regulatory process and make registration and label changes more efficient.

- **optimise risk communication about chemical products by improving the transparency of voluntary recalls**
    - The measures in the Bill will ensure that the APVMA must be informed if certain voluntary recalls are being conducted, where these relate to the matters set out in sections 5A to 5D of the Agvet Code (that is, the safety, efficacy, trade and labelling

criteria). The APVMA will then be required to publish such recalls. This will improve transparency and ensure a baseline of information is available to all stakeholders.

Consortium Comment: No specific comment, but would support in principle.

- **harmonise the need to inform the APVMA of new information (where it relates to the safety criteria) so that the same obligations apply to all holders and applicants**
  - Currently, information is 'relevant information' if it shows the active constituent or product may not meet the statutory criteria, or if it contradicts information in the application or information the APVMA has recorded in the record or the register.
  - These provisions are intended to ensure the regulator is aware of the latest information that is available and provide safeguards to protect public, animal and plant health and the environment from potential damage where new information about an Agvet chemical comes to light.

Consortium Comment: Now includes holders of off-label permits. Support the change but would encourage the APVMA to communicate with permit holders how this change will affect them. Particularly whether the process will be voluntary and *ad hoc* (i.e. report information as it is observed) or mandatory and set reporting times (i.e. requiring ongoing testing).

- **provide a more practical mechanism for dealing with minor variations in the constituents in a product, that normally occur in the manufacturing process**
- **provide the APVMA with more proportionate options for dealing with false or misleading information, and clarify what information must be included on a label**
  - now includes applications for off-label permits. Permits can be cancelled if false or misleading information is included in the application.
- **allow the holder of a suspended product to address the reason for the suspension**
- **fix anomalies in the regulation-making powers for the labelling criteria**

Consortium Comment: The above 4 only affect manufacturers and the APVMA.

- **simplify the APVMA's corporate reporting requirements**
- **make minor and machinery changes including removal of unnecessary and redundant provisions.**

Consortium Comment: The above 2 only affect the APVMA.