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Submission on Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012

Background

Agricultural chemicals and veterinary medicines

Agricultural chemicals (also known as pesticides) include a broad range of products that protect crops from a wide range of weeds, insects and pathogens. These chemicals are used in agricultural and forestry industries to ensure pest control is effective and so to aid industry productivity. In other contexts, agricultural chemicals are important in the protection of buildings, parks and infrastructure, as well as in households for the control of a range of pests.

Agricultural chemicals are also used in human health for protecting against disease vectors such as mosquitoes and rodents. Agricultural chemicals also play a role in protecting the environment from pests such as locusts, foxes and weeds.

Veterinary medicines, such as vaccines, antibiotics, worm treatments, lice treatments and some vitamins and minerals are important for the protection of livestock from pests and to treat a wide range of diseases and conditions. These products are also essential for maintaining the health and wellbeing of companion animals, including domestic pets and service animals.

National Registration Scheme

Agricultural chemicals and veterinary medicines (together, agvet chemicals) are regulated through a cooperative National Registration Scheme (NRS) for Agricultural and Veterinary Chemicals. The NRS was agreed on by the Australian Agriculture Council (now the Standing Council on Primary Industries) in 1991 and is described in a ministerial level intergovernmental agreement that was signed in September 1995.

The NRS is a partnership between the Commonwealth and the states and territories, with a shared division of responsibilities. Assessment and registration of agvet chemicals, as well as control of supply activities up to the point of retail sale, is undertaken by the Australian Pesticides and Veterinary Medicines Authority (APVMA) (a Commonwealth authority). Control of use of agvet chemicals after sale is the responsibility of individual states and territories.

The *Agricultural and Veterinary Chemicals Code Act 1994* (Code Act) contains as a schedule to it, the Agvet Code. Under the NRS, the Agvet Code operates in each state and territory to constitute a single national Agvet Code applying throughout Australia.

The Agvet Code, among other things, contains the detailed provisions allowing the APVMA to evaluate, approve or register and reconsider active constituents and agricultural and veterinary chemical products (and their associated labels). The provisions also allow the APVMA to issue permits and to licence the manufacture of chemical products. Other

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provisions in the Agvet Code provide for controls to regulate the supply of chemical products; and ensure compliance with and enforcement of the Agvet Code.

Roles and responsibilities of the APVMA

The APVMA is responsible for administering and managing the parts of the NRS that oversee registration, quality assurance and compliance of agvet chemicals up to and including the point of retail sale.

With input from other government agencies, the APVMA approves active constituents and agvet chemical products, undertakes reviews of existing approvals and registrations and monitors the compliance of approvals and registration up to and including the point of retail sale. The APVMA's processes provide assurance, through rigorous science based risk assessments, that agvet chemical use is safe for human and animal health and the environment. They also provide assurance that agvet chemicals will be effective and will not adversely affect Australia's ability to trade agricultural produce. Australia currently has around 9900 separate agvet chemical products registered, each of which contains one or more of around 1883 approved active constituents.

The APVMA's regulatory functions are defined by the *Agricultural and Veterinary Chemicals (Administration) Act 1992* (Admin Act) which established the APVMA; and the Code Act, together with its scheduled Agvet Code. These 2 Acts provide detailed operational procedures on the registration and management of agvet chemicals.

Objectives of the Bill

The Agricultural and Veterinary Chemicals Legislation Amendment Bill 2012 (the Bill), if enacted, would implement reforms to the approval, registration and reconsideration of agvet chemicals to modernise and improve the current regulatory arrangements and provide greater certainty to the community that chemicals approved for use in Australia are safe. The Bill makes it clear that the health and safety of human beings, animals and the environment is the first priority of the regulatory system.

The reforms aim to encourage the development of newer and safer chemicals by providing more flexible and streamlined regulatory processes with higher levels of transparency and predictability for business seeking approval for agvet chemicals to enter the market. The reforms should result in a more straightforward assessment process that is easier to understand and more cost effective to administer. In many cases, particularly for products of low regulatory concern, the reformed system as established by these amendments should be faster, deliver more predictable outcomes and result in improved health and environmental protection for the broader community.

The reforms also seek to provide greater assurance for all stakeholders about the safety of new and existing agvet chemicals. This is achieved by implementing a systematic approach to regular review of approvals and registrations, which is tailored to the Australian agricultural and veterinary chemicals market. The amendments in the Bill enhance the APVMA's ability to ensure compliance with its decisions and to manage issues of non-compliance.

Benefits to human health and the environment would flow particularly from improved access to newer and safer chemistry; increased scrutiny of currently available chemicals for their human and environmental health and safety impacts; and from improved mechanisms to ensure compliance with regulatory decisions. Human health benefits would accrue to people who are exposed to chemicals in their concentrated form through handling and use; or to

chemical residues in treated areas and in the food supply. Business would benefit through increased certainty over regulatory requirements and timeliness, reduced application requirements where permitted by appropriate risk management, improved data protection provisions and increased community confidence in regulatory outcomes.

Amendments made

The Bill amends the Admin Act, *Agricultural and Veterinary Chemicals Act 1994* (Agvet Act), Code Act and the *Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994* (Collection Act).

The amendments would:

- Enhance the consistency and transparency of agvet chemical approvals, registrations and reconsiderations through development, publication and implementation of a risk framework, which the APVMA must have regard to and legislative amendments to align regulatory effort with chemical risk
- Ensure the ongoing safety of agvet chemicals and improving the current agvet chemical reconsideration arrangements by implementing a mandatory re-approval and re-registration regime, designed to identify any potentially problematic chemicals while minimising any negative impacts on affected businesses
- Improve the assessment processes for agvet chemicals applications for approval, registration and variation, and improving the timeliness of agvet chemical approvals, registrations and reconsiderations
- Improve the ability of the APVMA to enforce compliance with its regulatory decisions by providing the APVMA with a graduated range of compliance enforcement powers and introducing a power to apply statutory conditions to registrations and approvals
- Improve consistency in data protection provisions and remove disincentives for industry to provide data in support of ongoing registration of agricultural and veterinary chemicals
- Address perceptions of a conflict of interest by providing for an agency other than the APVMA to collect the chemical products levy, should it be cost effective to do so.

The Bill also includes other amendments to remove redundant provisions and amend out of date provisions.

The Explanatory Memorandum explains the amendments made by the Bill in detail.

Reform context

Reforms identified

A number of inquiries, audits and consultation processes have informed the development of the Bill and the proposed reform measures.

In 2006, the Australian National Audit Office's *Performance Audit on the Regulation of Pesticides and Veterinary Medicines* and the APVMA made a number of recommendations in relation to the APVMA's regulatory functions, agvet chemical registrations, external scientific advice, monitoring product quality and cost recovery. Also in 2006, the Council of Australian Governments (COAG) recognised chemicals and plastics policy as a regulatory 'hotspot', and a Ministerial Taskforce was established to develop measures to achieve a streamlined and harmonised system of national chemicals and plastics regulation.

In 2008, the Productivity Commission's *Chemicals and Plastics Regulation Research Report* recommended improvements to agvet chemical products and the APVMA, which remain relevant today and to the proposed reforms outlined in the Bill, including that the APVMA:

- ensure that the costs of chemical assessments are commensurate with the risks posed by the chemicals concerned
- assessment priorities are directed to the most efficient management of the aggregate risk of all agvet chemicals
- should accelerate its chemical review program and work to eliminate the backlog for existing products identified for review
- should monitor the international developments on cumulative risk assessment methodology and policy, and investigate the feasibility of their implementation in Australia
- should make greater effort to recognise aspects of overseas hazard and risk assessments
- should apply data protection provisions for agvet products to the addition of new uses to registered products and to permit applications

Below is a description of the key reasons and drivers for the reforms outlined in the Bill.

Approvals and registrations of active constituents and chemical products

Aspects of the current approval and registration system lead to delays in assessing and approving agvet chemicals. In some cases, delays occur as a result of the APVMA focussing its resources on all aspects of the system rather than focussing on the high risk elements. In other cases delays occur because registrants submit inferior applications that the APVMA then provides assistance on improving.

As well, elements of the reconsideration process for approvals and registrations prolong chemical reconsiderations as applicants may unceasingly provide data to support a review, requiring the APVMA to delay the outcome of the reconsideration while it assesses new information. Chemicals under review remain on the market in the meantime.

Application quality

One of the objectives of the reforms is to place the onus on applicants to ensure their applications are of the required standard to be assessed, instead of inappropriately relying on regulator resources to replace the need for their own expertise. Making transparent the APVMA's principles and processes that apply to applications for approval or registration is the foundation stone for these improvements. This work is done through the risk compendium, which includes guidelines and requirements made for new sections 6A and 8B (Schedule 1 of the Bill). The APVMA is to further assist applicants in understanding the requirements that apply to their applications by offering upfront application assistance with applications prior to submission, with the cost of a reasonable amount of assistance set off against the fee for an application.

Division 2 of Part 2 of the current Agvet Code describes the process for granting or refusing approvals and registrations. Applications for approval of active constituents or labels or for registration of chemical products are made for section 11:

'(1) The application must:

(a) be in writing in or to the effect of the approved form; and

(b) contain, or be accompanied by, any information that the APVMA requires'

After the application is made the APVMA must make a preliminary assessment (s 11A) as to whether the application complies with s 11(1). If the application does not comply but if it can be rectified the APVMA must ask the applicant to rectify the application.

By allowing applicants to rectify deficient applications the current system provides an incentive, in terms of time, money and data requirements, for an applicant to make an application in an incorrect (less onerous) category in the hope it will be accepted. This places an unacceptable administrative burden on the APVMA, and results in a diversion of resources away from those applications that have been properly made, potentially impacting on the timeliness of their assessment.

The current section 11 also provides:

> '(3) At any time after an application has been made and before it has been determined, an approved person:
>
> ...
>
> (c) may give to the APVMA information additional to or varying information previously given to the APVMA'

Allowing applicants to provide new or additional information in relation to an application at any stage of the application process affects the timeliness of assessments and places a burden on the APVMA and partner agencies who are then obliged to take account of the information, often requiring them to undertake additional detailed assessment or re-evaluate part of their assessment. Currently, applicants regularly submit applications under less onerous assessment categories which may pass through the initial screening process more quickly, and then later make changes to the application during the evaluation process, adding delay and complexity to the assessment.

Timeliness

Section 165 of the current Agvet Code requires:

> '(1) When an application is made under this Code to the APVMA, the APVMA must determine the application within a period stated in, or determined in accordance with, the regulations.'

The Agvet Code also implements a 'stop the clock' provision for the time it takes applicants to respond to a requirement made of them (at para 165(2)(a)).

These provisions, in combination with the provisions discussed above, have resulted in a system whereby the time for the clock to start on an application assessment occurs some time after the application is submitted. Even then the clock is sometimes stopped to address defects found later in the assessment process. The total elapsed time between initial submission of the application and determination of the result regularly exceeds the prescribed time, sometimes substantially.

The Bill amends the application process to require applications to be complete and of suitable quality before they are assessed. The Bill also provides for all steps of the application process to be included in the timeframe for completing assessment of an application.

Enforcement

The existing statutory framework for the APVMA limits its capacity to manage compliance through monitoring and enforcement. Modern compliance systems use a wide range of tools to address instances of non-compliance in an appropriate and cost-effective manner. These

tools present alternatives to criminal prosecution and provide for a response by the regulator that is proportional to the risk posed by the non-compliant behaviour.

The provisions within the existing framework are not currently aligned with the contemporary compliance needs or expectations of government, community or industry. The existing provisions provide limited avenues for responding to non-compliance. The current statutory framework lacks any graduation between passive enforcement tools (such as warning letters) and stronger actions (such as suspension, cancellation, product recall or criminal prosecution).

The Bill amendments build on existing provisions under the Agvet Code. The existing provisions are important to act as a deterrent to actions that could result in serious impacts on human, animal and environmental health and trade. The aim is to provide the APVMA with a range of compliance powers that it can use to implement its compliance strategies.

Data protection

Data protection is a common feature of agricultural and veterinary chemical regulation in countries that have comparable regulatory systems to Australia. Regulatory data is required to be protected from unfair commercial use by the World Trade Organisation (WTO) under its Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the data should not be disclosed in an inappropriate manner. Investment in regulatory data can require significant resources and the protection of these data encourages innovation in new and existing agvet chemicals, and supports the ongoing registration of existing chemical products.

As the time taken to collect regulatory data and have it assessed by the regulator diminishes its value, the protection of these data encourages innovation in agricultural and veterinary chemicals. In the case of new chemical products this means that the APVMA cannot rely on data it holds (that was given in connection with an earlier application or reconsideration) to register a product without the data owner's permission and before any protection period has elapsed.

The current provisions for information provided to a reconsideration are overly complex, inadequate and are inconsistent with data protection provisions available in relation to an application for an approval or registration. Reform is required to encourage submission of data in support of reconsiderations. Reform would limit disincentives to invest in innovative product development and to improve the productivity of Australia's agri-food industries. Measures are required to reduce the likelihood that chemicals will be unnecessarily removed from the market as a result of any re-registration scheme.

Reform is also required to data protection provisions for approvals and registrations to prevent loss of protection if an application is refused or withdrawn. The current arrangements work as an incentive to keep applications active rather than refuse them because of the data protection consequences of a refusal. The Bill provides for protection of information from the time it is given until after a period of protection has expired once the information is relied on to grant an application. The change is not intended to impact on the APVMA's ability to use data once the period of protection has expired.

Levy collection

The APVMA collects the levy applied to sales of agvet products, leading to perceptions of a conflict of interest. It would be appropriate to address this perception and potentially provide

for more efficient collection of the levy by allowing another Commonwealth agency to undertake the collection task. No change to the levy structure or rate is proposed by the Bill.

Better Regulation Ministerial Partnership

The proposed reforms incorporate work undertaken via a Better Regulation Ministerial Partnership (the partnership) between the Minister for Agriculture, Fisheries and Forestry and the Minister for Finance and Deregulation, as announced at the ABARE Outlook conference in March 2010.

The Bill builds on earlier progress that has already been made via the partnership, with the legislative changes in the *Agricultural and Veterinary Chemicals Code Amendment Act 2010* in June 2010. This included a simplified process for applicants to make minor variations to chemical approvals or registrations (such as changing pack size); allowing companies to make minor changes to chemical labels (such as changing a logo); and removing the requirement on registrants to notify the APVMA of an approved person.

The Bill accompanies a number of COAG 'early harvest' reforms for agvet chemicals that were identified and which the Australian Government (in conjunction with states and territories) has progressed through reforms that are being implemented separately.

Public Consultation

The reforms have been informed by extensive stakeholder consultation. Chemical industry groups, environmental organisations, primary producer associations, Commonwealth, state and territory agencies were all involved in discussions about the Bill.

Three rounds of public consultation were conducted on the reforms and associated Bill. The first round of public consultation occurred from mid November 2010 to early February 2011 about the policy discussion paper, *Better Regulation of Agricultural and Veterinary Chemicals*. Ninety two submissions were received on the discussion paper.

Further public consultation with an exposure draft of the legislation occurred from 15 November 2011 to 29 February 2012. Over 70 submissions on the exposure draft legislation were received and considered.

The Bill was revised and released again as a revised exposure draft in September 2012. The revised Bill included amendments to address issues raised during the previous round of consultation. A further 23 submissions were received by the close of the consultation period to inform final amendments to the Bill.