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**Australian Pesticides and
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APVMA regulatory science strategy

Consultation Draft

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FOREWORD

The APVMA is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemicals proposed for supply and use in Australia. We evaluate the safety and performance of chemicals intended for sale in Australia to ensure that the health and safety of people, animals, crops and the environment are protected.

High quality regulatory science is a critical component of the work of the APVMA.

The APVMA identifies issues, assesses chemical risks, and makes regulatory decisions, even when scientific evidence is incomplete. We need to demonstrate that we have considered the best possible scientific advice, and explain the basis for our decisions to a public which includes those who have limited knowledge of the assessment process that underpins APVMA decisions.

There are a number of strategic areas we will focus on, including:

- increasing our scientific capacity and capability
- building national and international linkages
- enhancing communication and engagement
- enhancing our ability to identify and respond to emerging regulatory issues
- improving regulatory science methodologies, and
- improving our regulatory science performance.

The activities outlined in this strategy builds on our strong commitment to enhancing our scientific capability. This commitment is embodied in the establishment of an Office of the Chief Scientist in 2014. Through engagement with national and international networks, the Office identifies issues and trends that impact on APVMA's regulation of agvet chemicals and helps ensure that our science frameworks and practices continue to meet appropriate standards. It develops projects and initiatives to enhance scientific capability at the APVMA.

Through the Regulatory Science strategy, the APVMA will make more effective use of scientific expertise and knowledge to help stimulate innovative approaches to regulation, enhance regulatory science quality, develop the APVMA as an organisation which is seen by technically-qualified people as an employer of choice, contribute to enhanced productivity, and help promote community confidence in Australia's agvet chemical regulator.

1 INTRODUCTION

This strategy outlines how the APVMA will further enhance its scientific capacity and resources to fulfil its role of regulating agricultural and veterinary chemicals in order to protect the health and safety of people, animals and crops, the environment and trade.

It provides a map for how the APVMA will implement its commitments in the 2015-19 Corporate Plan to ensure that our regulatory decision making is underpinned by high quality regulatory science.

Table 1: APVMA vision and mission

VISION
Australians have confidence that agricultural and veterinary chemicals are safe to use
MISSION
To protect the health and safety of Australia — its people, animals and environment — and support Australian agriculture by taking a scientific and risk-based approach to regulating agricultural and veterinary chemicals.

1.1 Regulatory science defined

A number of definitions of 'regulatory science' have been published¹. There is a difference between regulatory science and what may be referred to as 'conventional science' or 'research science'.

Conventional science involves the application of the scientific method for the purpose of understanding some physical, chemical or biological phenomena. It tends to be curiosity-driven, forward looking and speculative. New results generate new ideas, with any uncertainty addressed through the conduct of additional research to the point where satisfaction is only attained when everything is understood.

Regulatory science involves a pragmatic application of the scientific method for the purpose of making a decision about whether to allow something (eg chemicals) to be used within the defined legislative framework and timeframes.

In the context of the work of the APVMA, regulatory science is a broad term relating to chemical, biological and other product regulations, regulatory standards, technical policies and procedures. It is a systemised body of knowledge compiled and utilised by regulatory agencies world-wide, with a focus on the protection of human health (public health and/or occupational health and safety) and the environment. Scientific methods employing empirical and causal evidence are utilised in the formulation of technical policies, risk assessment methodologies, and in evaluation and approval of the products an agency regulates. Regulatory science can encompass both pre-market and post-market activities.

¹ Examples include those published by the US Food and Drug Administration (FDA) at www.fda.gov/downloads/scienceresearch/specialtopics/regulatoryscience/ucm268225.pdf and the European Medicines Agency (EMA) at www.ema.europa.eu/docs/en_GB/document_library/Other/2013/03/WC500139888.pdf

Regulatory science does not include regulatory affairs (the administrative aspects of regulation) or regulatory law (the legal aspects of regulation).

What differentiates regulatory science from conventional science is that decisions are based on analysis and interpretation of existing scientific knowledge and, where necessary, assumptions to address data gaps or uncertainty. Regulatory scientists do not generate new lines of enquiry to answer questions, instead relying on available information (provided by applicants or in the literature) to make a decision one way or another.

While regulatory science incorporates a variety of scientific disciplines, it is in itself a specialised field of science. Most regulatory scientists have trained and worked in conventional scientific research, and additionally have gone through a process of on-the-job training, mentoring and ongoing peer support to transition into regulatory science. Regulatory scientists are trained in risk analysis - comprising risk assessment, risk management and risk communication - as well as being trained in public administration and regulatory decision making.

Regulatory agencies have to consider the findings of conventional (or basic) scientific research and apply any relevant findings to regulatory science which then directs the tasks of regulators in conducting risk assessments of applications for approval to market new pesticide and veterinary medical products. (Figure 1)

Figure 1: Regulatory Science



2 STRATEGIC INITIATIVES

APVMA'S REGULATORY SCIENCE VISION

To continuously improve APVMA scientific capability to support quality regulatory decision making

STRATEGIC AREAS OF FOCUS

- 1 Increasing our scientific capacity and capability
- 2 Building national and international linkages
- 3 Enhancing stakeholder communication and engagement
- 4 Enhancing our capability to identify and respond to emerging regulatory issues
- 5 Improving regulatory science methodologies
- 6 Improving our regulatory science performance

2.1 Increasing our scientific capacity and capability

The APVMA has to recruit and retain technical experts across a broad range of disciplines relevant to its risk analysis role; staff with the appropriate skills and experience are needed to obtain, interpret and provide high quality scientific advice.

In order to undertake high-quality risk assessments it is essential that we maintain and enhance our scientific capacity and capability in relation to our staff (including the staff of our advisory agencies) as well as the resources and the tools used to regulate agricultural and veterinary chemicals.

To achieve this, the APVMA will:

- ensure our regulatory science framework and risk-assessment tools are up-to-date, fit-for-purpose and relevant to the regulation of agvet chemicals in Australia (viz. approval of active constituents, registration of agvet chemical products, and the issuing of permits)
- ensure that new and existing technical staff members are given appropriate training in risk assessment and our risk assessment tools - and how risk assessments are used to develop risk management options
- ensure that our risk assessments are proportionate to the risks being managed
- utilise external expertise in relevant fields that complements the in-house expertise
- maintain collaborative links with other regulatory agencies, both national and international
- ensure ongoing access to relevant on-line resources, including scientific journals and databases
- attract and retain highly-trained technical staff by offering appropriate professional development and career opportunities
- promote the APVMA as an employer-of-choice by highlighting the diversity of expertise required in agvet chemical regulation.

Case study—science fellows and visiting scientists

APVMA's Science Fellows Program has the primary objective of enhancing the quality of regulatory science and building public confidence in the APVMA. Science Fellows are eminent national and international scientists in key disciplines that are relevant to agricultural and veterinary chemical regulation. When the Science Fellows Program was initially established, the Science Fellows were the sole providers of high-level external scientific expertise to the APVMA. Subsequently, a new model was established that involved two groups of external experts, Science Fellows and Visiting Scientists. The two groups perform somewhat different, but complementary, functions.

Science Fellows provide high-level independent advice on complex and contentious regulatory issues; assist in the development of regulatory science policy; provide advice in relation to staff training; and speak at APVMA Science Fellows symposia. Visiting Scientists deliver training to staff. When available, staff can access them for advice on specific risk assessments. Training materials presented by Visiting Scientists are made accessible on the intranet.

The Veterinary Medicines Science Fellows' work is supported by a Veterinary Medicines Expert Advisory Panel (VMEAP). The VMEAP complements the regulatory science activities of APVMA's veterinary risk assessors and provides a useful consultative mechanism.

2.2 Building national and international linkages

The APVMA will initiate and maintain strong linkages with external experts in relevant fields that complement the in-house expertise of the APVMA and enhance its capacity to regulate agvet chemicals in an effective, efficient and timely manner. Scientists in academia and research institutes have always worked as part of a global network – and this increasingly needs to be the case for staff in regulatory agencies. Working together with other regulatory scientists to share ideas and information improves the quality and robustness of regulatory science by accessing a range of views and ideas across a larger group of regulators; co-operation also promotes more effective use of resources.

Developing linkages and networks with other regulatory agencies, with research scientists in academia and with industry innovators will assist in ensuring that APVMA staff has access to the best available information and data to make sound and defensible regulatory decisions. The development of networks also assists in identifying emerging risks related to the use of agvet chemicals.

To continue to build and enhance our technical networks, the APVMA will:

- develop new and enhance existing relationships with relevant national and international regulatory agencies to facilitate the exchange of information and encourage worksharing
- maintain existing and build new relationships with relevant national and international scientists to increase our access to expert advice on specific aspects of agvet chemicals risk assessment
- while preserving our impartiality and independence, maintain and build transparent and constructive links with the agvet chemical industry, including sharing knowledge and information in relation to test methodologies, chemical-use practices in the agricultural and animal husbandry industries, and the types of data necessary to conduct robust risk assessments
- participate in committees of international organisations and expert working groups
- as a responsible and respected regulator, contribute to capability-building globally, but with a regional emphasis.

Case study—the regulatory science network

In 2011 the APVMA played a key role in the formation of the Regulatory Science Network (RSN) which brings together scientists from nine Australian federal government agencies responsible for regulating chemicals and biological agents. APVMA's participation is aimed at strengthening our regulatory science and risk analysis capability. The application of risk analysis principles differs somewhat between agencies, primarily due to differences in legislative frameworks and the regulatory contexts in which they operate. Communicating these differences helps our risk assessors to better understand risk analysis principles.

In view of the fact that lessons learned from the operation of the RSN to date could provide a model for similar cooperative intra-and inter-national agency liaison on regulatory science issues, the APVMA presented a poster titled Finding Common Ground: Establishment of an Australian Regulatory Science Network at the 13th IUPAC (International Union of Pure and applied Chemistry) Congress of Pesticide Chemistry in San Francisco in 2014.

Case study—VICH

The International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) is an international program to provide guidance on technical requirements for registration of veterinary medicinal products. VICH was established in 1996 as a means of collaboration primarily between the regulatory authorities and the animal health industry of the EU, Japan and the USA. The regulatory authorities and animal health industry of Australia, New Zealand, Canada and South Africa have actively participated as VICH observer members.

An APVMA representative participates in VICH Steering Committee meetings since it provides an opportunity to influence international standards relating to registration requirements of veterinary medicines. It also allows us to gain a better appreciation of standards and risk assessment methodologies applied to veterinary medicines by overseas regulatory agencies. The adoption and implementation of VICH guidelines, where it is considered appropriate to do so, is an important element of the APVMA's commitment to harmonise its data requirements for veterinary medicinal products with those of overseas agencies.

2.3 Enhancing stakeholder communication and engagement

The APVMA has a diverse range of stakeholders who have different levels of knowledge about regulatory science and the regulatory system for agvet chemicals in Australia². The APVMA needs to engage with the public in order to raise the general level of awareness and understanding about the assessment process for agricultural and veterinary chemicals, especially its focus on human health and the environment.

The APVMA needs to use a range of communication methods to ensure that all stakeholders have appropriate access to information on regulatory science issues and have the opportunity to provide comment on proposed assessment methods and on risk management options. The APVMA must ensure that credible and independent scientific information is accessible to stakeholders so that they are better able to make informed decisions about issues that might affect them.

To promote our science and to ensure that a range of views are considered, the APVMA will:

- facilitate linkages with our regulated stakeholders so that they are well informed about the regulatory framework within which they operate
- ensure that the reasons for our regulatory decisions are transparent and in compliance with the Agvet Code.
- communicate regulatory science to our stakeholders in an appropriate manner
- engage with our stakeholders and be open to a range of views

respond promptly to enquiries from the public about issues relating to agvet chemicals.

Case study—publication of an ‘our science’ web page

An APVMA ‘Our Science’ web page was developed to facilitate the posting of regulatory science information and items which may be of interest to our stakeholders. Core content defines what ‘regulatory science’ is, provides the risk analysis framework which underpins our risk assessment methodology, and sets out the principles of good regulatory science practice. The page also outlines the role of APVMA’s Office of the Chief Scientist, lists APVMA’s Science Fellows and specialist subject advisers, and provides information about Australia’s Regulatory Science Network (RSN).

² The APVMA has a range of stakeholders including the community, the chemicals industry, Australian, state and territory governments, other users of agricultural chemicals and veterinary medicines, and other national and international regulators.

2.4 Enhancing our capability to identify and respond to emerging regulatory issues

In its work the APVMA identifies emerging agvet chemical issues which may impact existing or future risk assessments and decisions and then responds appropriately. Enhancing our ability to foresee issues will help prepare the APVMA for any new issues which may arise.

The APVMA will:

- continue to identify and respond (if appropriate) to emerging issues relating to agvet chemicals and their regulation, both here and overseas
- maintain and improve our capability to identify and investigate emerging regulatory issues
- build linkages with national and international agencies to share information about emerging issues.

The APVMA needs to inform itself about scientific and technical advances which may ultimately lead to the development of novel ways of controlling pests and diseases in plants and animals. New technologies may require the development of new regulatory frameworks.

The APVMA recognises the importance of Research and Development in the programs of many agvet chemical companies and the need to gain an awareness from them of techniques and/or products in the development pipeline.

The APVMA will:

- identify scientific and technical advances in areas which may lead to the development of novel agvet chemicals or pest-control technology requiring new approaches to their regulation; this will be done by scanning the literature and by constructive interactions with industry and academia
- develop and test model frameworks for the assessment and regulation of products of emerging technologies
- identify scientific and technical advances which may ultimately impact regulatory frameworks and/or methodologies
- build linkages with other agencies to share information about the regulation of new technologies.

Case study—regulation of new RNA interference technology in agvet chemical products

RNA interference (RNAi) is a biological process in which small RNA molecules inhibit gene expression, typically by causing the destruction of specific messenger RNA (mRNA) molecules. It is commonly referred to as post-transcriptional gene silencing (PTGS); that is, messenger RNA is transcribed from the DNA gene but before the message is translated into proteins by ribosomes, the mRNA is blocked or otherwise destroyed by a specific non-coding microRNA (miRNA). RNAi's are being developed as insecticides to protect plants, either by genetic modification of the plant to incorporate the machinery to synthesise RNAi molecules specifically directed against insect predators, or by topical application (spraying) of RNA molecules to the plant; most plants are able to absorb double-stranded RNA molecules which are subsequently processed to miRNAs and then distributed throughout the plant. In cooperation with researchers at the Commonwealth Scientific and Industrial Research Organisation (CSIRO), the APVMA has started to consider the issues which may need to be taken into account in regulating pesticides and veterinary medicines based on PTGS. The APVMA has contributed to several CSIRO workshops on RNAi technology and CSIRO scientists presented a seminar at the APVMA on RNA interference – an emerging technology for controlling pests and diseases in animals and plants.

2.5 Improving regulatory science methodologies

The APVMA will pursue innovation in regulatory science practice by constantly striving to improve the hazard and exposure assessment tools we use and the way in which we conduct risk assessments.

To maintain an ongoing and effective regulatory system the APVMA will:

- consider our current risk assessment tools to fulfil our regulatory role in evaluating novel pesticides and veterinary medicines
- regularly investigate new risk assessment approaches to see if the regulatory science methods we use remain appropriate
- communicate with other government agencies (federal and state/territory) to exchange ideas about risk assessment and best regulatory practice
- work collaboratively with government regulatory agencies in countries with similar regulatory systems to improve regulatory methodologies
- contribute to the work of international organisations involved in chemical risk assessment and accept new test methods or adopt new risk assessment approaches when consensus had been reached.

Case study—guidance document on conducting insect pollinator risk assessments in Australia

In 2015 a guidance document or 'roadmap' on conducting insect pollinator risk assessments, for use by the APVMA and its environmental advisory agency and external advisors, was developed by the APVMA. The roadmap primarily draws upon a North American risk assessment document for pollinators published in 2014 but utilises additional information provided in a very detailed 2014 European Food Safety Authority (EFSA) guidance document. The roadmap outlines an up-to-date risk assessment methodology which can be amended as new bee testing protocols are developed and approved.

Genomic recombination

For more than 40 years prior to 2007, two vaccines containing native strains of infectious laryngotracheitis (ILT) virus were used to control the disease in Australia. In 2007, a vaccine containing a strain of European origin was registered and rapidly became widely used. Shortly afterwards, outbreaks of ILT in chickens became more prevalent. In 2012 APVMA Science Fellow, Professor Glenn Browning, APVMA Visiting Scientist, Dr Joanne Devlin, and their colleagues from the Asia-Pacific Centre for Animal Health at the University of Melbourne found that two different vaccine strains of ILT virus had recombined to generate more virulent viruses. This led to flock mortalities of up to 20% in chicken farms in NSW and Victoria. Previously the risk of recombination of live attenuated vaccine viruses in the field had been considered by regulatory agencies worldwide to be negligible. As a result of this finding, the regulation of live attenuated vaccines must now take into account the proven potential for recombination. Accordingly, the APVMA is developing regulatory processes to investigate the virulence of overseas parent strains prior to their approval for use in animal vaccines.

2.6 Improving our regulatory science performance

We conduct our work according to APVMA's [Standard on good regulatory science](#) and have a number of processes and procedures in place to help ensure the integrity of our regulatory decision-making. The [organisational structure of our technical teams](#) (Scientific Assessment and Chemical Review, Registration Management and Evaluation, and Office of the Chief Scientist) provides for a number of opportunities for peer review of draft human health, environmental, residues, chemistry and efficacy assessments prepared by our advisory agencies, by external consultants or (for chemistry and residues assessments) by APVMA staff.

We seek formal peer review of key scientific reports from both domestic and international experts, provided that they are independent of any conflicts of interest. Our participation in international workshare arrangements with overseas regulatory also introduces a peer-review element into our evaluations and provides a yardstick against which to measure the quality of our risk assessments.

The APVMA reviews, on an ongoing basis, its technical policies and risk assessment methodologies to see if they can be improved, or removed if no longer necessary or appropriate.

To help improve our performance the APVMA will:

- utilise our Science Quality Committee (SQC) and Registration Quality Committee (RQC) to consider the quality of our scientific processes and regulatory outputs.
- implement a [framework to provide lower regulatory approaches to registration](#)
- increase our [use of international data, assessments, standards and decisions](#)
- improve the volume and detail of technical guidance materials which explain how the APVMA uses information and valid scientific argument to ensure the [statutory criteria can be satisfied](#)
- monitor our performance by implementing the framework being developed to provide assurance about the quality of APVMA decision making and address any systematic issues in the quality of our science which become apparent.

Case study—establishing an office of the chief scientist within the APVMA

In late 2014 the APVMA established an APVMA Office of the Chief Scientist. One aim was to help ensure that our regulatory science frameworks and standards continue to meet appropriate national and international standards. Through engagement with national and international scientific and regulatory networks, the Office identifies issues and trends that may impact on the integrity of APVMA's regulatory science frameworks and standards, and develops appropriate projects and initiatives to improve our scientific capability and performance. The Office also provides the Chief Executive Officer and senior staff direct access to independent, expert advice on regulatory decisions and scientific aspects of the APVMA's regulatory framework.