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Australian Pesticides and Veterinary Medicines Authority

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APVMA Regulatory Science Strategy

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FOREWORD

The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for assessing and registering agricultural and veterinary (agvet) chemicals proposed for supply and use in Australia. The APVMA evaluates the safety and performance of chemicals intended for sale in Australia to ensure 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. The authority must demonstrate the best possible scientific advice is always considered and explain the basis for our decisions to the public. This explanation also includes those who have an extensive knowledge of the hazard and risk assessment for chemicals, in addition to those who have a limited understanding of the process that underpins APVMA decisions.

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

- boosting regulatory science capacity and capability
- building national and international links
- enhancing stakeholder communication and engagement
- extending the ability to identify, monitor and respond to emerging regulatory issues
- improving regulatory science methodologies
- monitoring and enhancing regulatory science performance.

The activities outlined in this strategy build on the organisation's strong commitment to enhancing 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 the APVMA's regulation of agvet chemicals. It helps ensure that science frameworks and practices continue to meet appropriate standards and develops projects and initiatives to enhance scientific capability at the APVMA.

Through this strategy, the APVMA will make more effective use of scientific expertise and knowledge to help stimulate innovative approaches to regulation and enhance regulatory science quality. It will help develop the APVMA as an organisation that employs technically-qualified people and increase community confidence in Australia's agvet chemical regulator.

This regulatory science strategy is consistent with the current APVMA operational plan. It is a high-level document, outlining the APVMA's general approach to regulatory science. More detailed technical documents can be found on our website, such as the APVMA data guidelines.

While this strategy will focus on the APVMA's regulatory science performance, it will also consider the quality of our assessments, which depend on the quality of the data submitted by applicants. Therefore, the APVMA needs to work with applicants to improve the quality of their submissions and in turn, the consistency and timeliness of evaluations.

In preparing this strategy, the APVMA is mindful of the Australian Government's Industry Innovation and Competitiveness Agenda and the National Innovation and Science Agenda. Both agendas note that:

- regulation should be efficient, responsive and innovative
- innovation and science should be at the centre of government, including innovation in service delivery and provision of data
- change is being driven by rapid advances in computer processing power and data storage capacity
- if trusted international standards or risk assessments are available, regulators should not impose additional regulatory requirements unless it can be demonstrated that there is a good reason to do so
- Australia needs to increase links with key economies to help improve business performance.

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, 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

Regulatory science involves a practical and consistent 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. It needs to recognise and describe the uncertainties of the risk assessment in a manner that informs the regulatory decision.

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.

Regulatory science does not include regulatory affairs (the administrative aspects of regulation) or regulatory law (the legal aspects of regulation). While it is not the role of regulatory scientists to establish overarching government regulatory policy, they do have a responsibility to inform policy makers who establish and revise the regulatory framework within which assessments are performed and decisions are made.

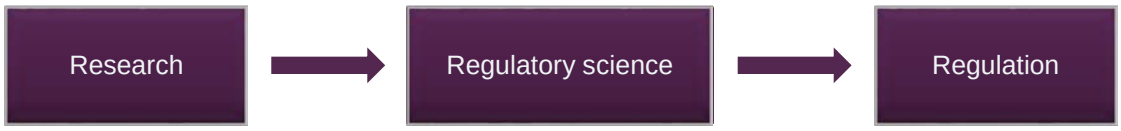
Regulatory science differs from research science in that decisions are based on analysis and interpretation of existing scientific knowledge and—where necessary—use of conservative assumptions, based on a precautionary approach to deal with data gaps or uncertainty. It is uncommon for regulatory scientists to instigate new lines of

enquiry by conducting their own scientific experiments or trials. They rely on information provided by applicants[1] or generated by research scientists and published in the peer-reviewed scientific literature to make a decision.

While regulatory science incorporates a variety of scientific disciplines, it is a specialised field of science. Most regulatory scientists have trained and worked in scientific research and have experienced 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.

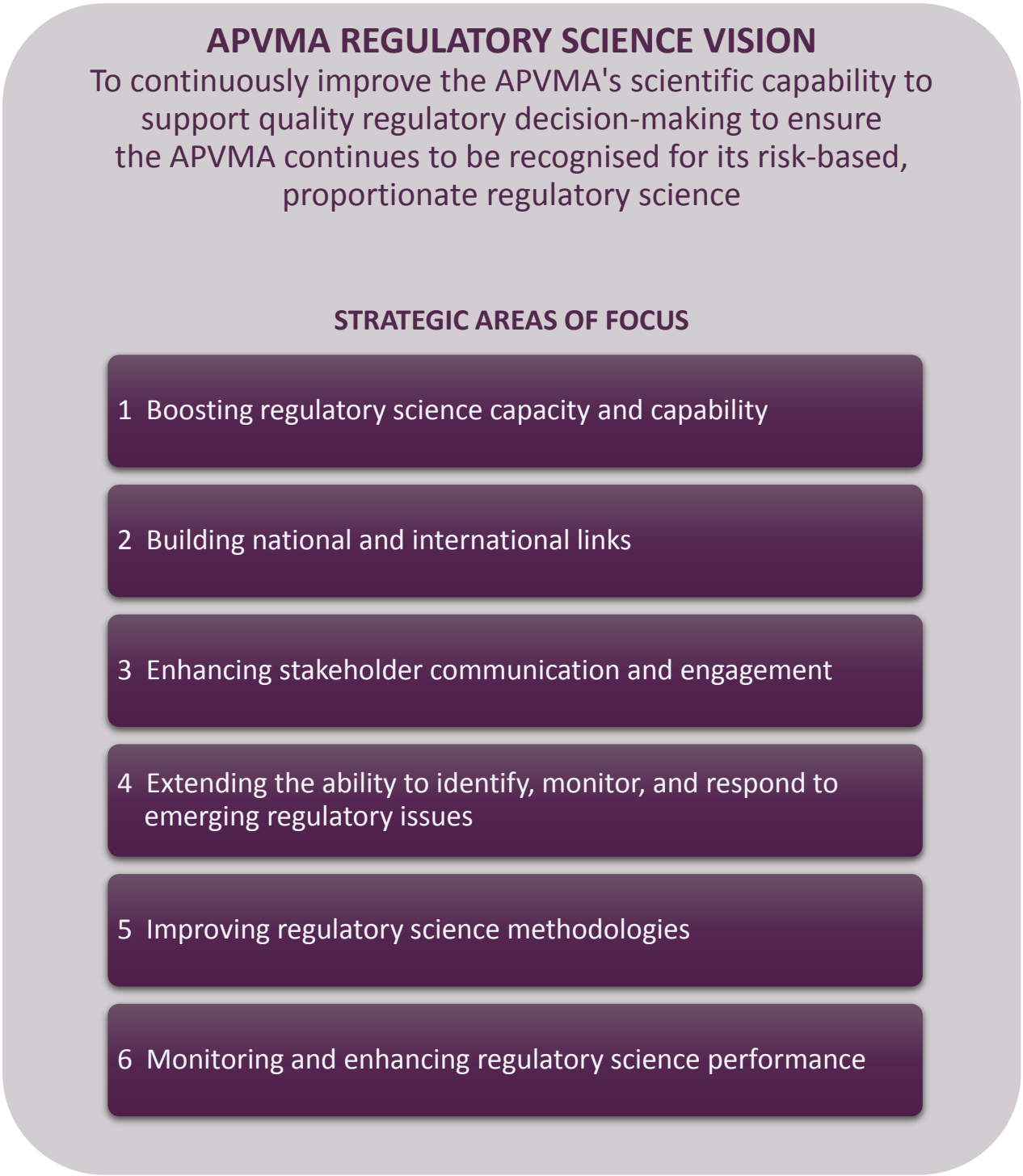
Regulatory agencies have to consider the findings of scientific research and apply any relevant findings to regulatory science which then directs the tasks of regulators in conducting risk assessments of applications for approval to market new pesticide and veterinary medical products (Figure 1).

Figure 1: Regulatory science



[1] Information and data are provided to the APVMA when companies make an application for approval of a new agvet active constituent or for registration of a new product. Companies are also required to provide new information or data when requested to do so by the APVMA, in order for it to conduct a risk assessment.

2 STRATEGIC INITIATIVES



The following text outlines how the APVMA plans to address the six strategic areas of focus. Within each strategy there are some overlaps with activities/focus areas in the other strategies.

2.1 Boosting regulatory science capacity and capability

The APVMA must recruit and retain technical experts across a broad range of disciplines relevant to its risk analysis role; staff with 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 the APVMA maintains and enhances scientific capacity and capability in relation to its staff—including advisory agency staff—as well as maintaining and enhancing the resources and the tools used to regulate agricultural and veterinary chemicals.

To achieve this, the APVMA will:

- investigate innovative methodologies and approaches to chemical risk assessment and regulatory science
- 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[2], including in risk assessment—and how risk assessments are used to develop risk management options
- utilise external expertise in relevant fields that complement our 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

The primary objective of the APVMA's Science Fellows Program is to enhance the quality of regulatory science and build public confidence in the APVMA. Science Fellows are eminent national and international scientists in key disciplines, 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. Both groups provide high-level independent advice on complex and contentious regulatory issues (eg antimicrobial resistance), assist in the development of regulatory science policy and provide advice in relation to staff training.

[2] APVMA risk assessors and risk managers require a broad knowledge, including an understanding of modern farming practices, since the way agvet chemicals are used in agriculture and animal husbandry will have a bearing on their human health and environmental risk assessments.

In 2010, four APVMA Fellows in Nanoscience were appointed. These experts provide advice, both on an individual basis and collectively as the APVMA Nanotechnology Expert Advisory Panel, on the regulation of nanotechnology products in agriculture and animal husbandry.

In view of the importance of external expert advice to its regulatory science role, the APVMA regularly considers other possible ways of accessing such advice.

2.2 Building national and international links

The APVMA will initiate and maintain strong links with external experts in relevant fields that complement the in-house expertise of the APVMA. Access to external experts will 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. 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; collaboration also promotes more effective use of resources.

Developing links and networks with other regulatory agencies, with research scientists in academia and with innovative industry players will help ensure that APVMA staff have access to the best available information and data to make sound and defensible regulatory decisions. The development of networks assists in identifying emerging risks related to the use of agvet chemicals.

Efficient and effective internationally-harmonised best-practice regulation helps deliver:

- increased public confidence in government regulatory agencies
- greater certainty for the regulated industry through reduced costs and reduced time-to-market (consistent with the Australian Government's policy of accepting trusted International standards and avoiding unnecessary Australian-specific regulatory approaches and requirements).

The APVMA will:

- develop new and enhance existing relationships with relevant national and international regulatory agencies to facilitate the exchange of information, encourage work sharing, and globally harmonise data requirements and test methods
- maintain existing and build new relationships with relevant national and international scientists to increase access to expert advice on specific aspects of agvet chemicals risk assessment
- participate in relevant scientific or advisory bodies, where appropriate to the APVMA regulatory role
- while preserving the APVMA's 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
- 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 eight Australian federal government agencies responsible for regulating chemicals and biological agents. The APVMA's participates in the RSN to strengthen its 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 each operate. Communicating these differences has helped our risk assessors to better understand risk analysis principles. The RSN plans to make the presentations from its workshops and symposia more widely available; presentations from its July 2015 symposium on risk governance (ie the application of good governance principles to the identification, assessment, management and communication of risks) are publicly available.

The operation of the RSN provided a model for similar cooperative intra- and inter-national agency liaison on regulatory science issues. With this lesson in mind, 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 as they provide an opportunity to influence international standards regarding registration requirements of veterinary medicines. The representative also gains 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 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 including the community (and community groups), the chemicals industry, Australian state and territory governments, users of agricultural chemicals and veterinary medicines, and national and international regulators. They have different perspectives and differing levels of knowledge about regulatory science and the regulatory system for agvet chemicals in Australia. In particular, 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 all stakeholders have appropriate access to information on regulatory science issues and have the opportunity to provide comment on proposed assessment methods and risk management options. The APVMA must ensure that credible and independent

scientific information is accessible to all stakeholders so they are able to make informed decisions about issues that might affect them.

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

- facilitate links with, and training opportunities for, stakeholders so they are well informed about the regulatory framework in which they operate
- ensure the reasons for regulatory decisions are transparent and comply with the Agvet Code
- communicate regulatory science to all stakeholders in an appropriate manner, including pro-active communications about risk assessment and risk management, to raise awareness of relevant agvet chemical issues
- engage with 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 has been developed to provide access to the APVMA's regulatory science information 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 RSN.

2.4 Extending the ability to identify, monitor and respond to emerging regulatory issues

'Emerging regulatory issues' can include new technologies deployed in crop production and animal husbandry as well as innovative regulatory practices and risk assessment methods. The APVMA must be aware of scientific and technical advances, which may ultimately lead to the development of new ways of controlling pests and diseases in plants and animals. New technologies may require the development of different regulatory frameworks.

Changes in agricultural and veterinary practices can lead to the need to review the approvals and labels of existing agvet chemical products while improved exposure and risk-assessment methodology could lead to revisions of prior risk assessments and regulatory decisions. Enhancing the ability to foresee issues will help prepare the APVMA for any new concerns that may arise.

The APVMA will:

- maintain and improve the organisation's capability to identify, investigate and respond to emerging issues relating to agvet chemicals and their regulation
- build links with national and international agencies to share information about emerging issues and the regulation of new technologies, in the areas of the APVMA's responsibility
- 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.

Identifying scientific and technical advances in areas relevant to the APVMA will be done by reviewing scientific publications and by constructive interactions with relevant experts in academia and industry[3].

In responding to emerging scientific and regulatory issues related to its legislated responsibilities in the area of agvet chemical risk assessment, the APVMA is cognisant of the Australian Government's Innovation and Science Agenda, which aims to stimulate and encourage innovation by Australian industry. In cooperation with other regulators and external stakeholders, the APVMA is involved in the development and drafting of guidelines on risk assessment approaches for new agvet chemical products. Industry will then have greater certainty that new technology has a clear regulatory pathway and will not be held up for an indeterminate length of time while regulation 'catches up' with the technology.

Similarly, the development and adoption by the APVMA of innovative regulatory methodologies utilising real-world datasets to better estimate exposure and risk will encourage industry to use these methods to more comprehensively assess the possible risks arising from the proposed introduction of new chemicals and products to the market.

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) and other regulatory agencies overseas, 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.

To this end 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'.

[3] The APVMA recognises the importance of research and development to innovative agvet chemical companies. Thus, industry scientists can be another source of technical advice which can help inform independent regulatory risk assessments.

2.5 Improving regulatory science methodologies

Regulatory science is the foundation of decision-making at the APVMA. As new discoveries yield increasingly complex agvet chemical products, the APVMA's regulatory scientists and consultants need to make well-informed decisions about these products. Advancements in science not only lead to better products but also to better ways of testing and evaluating them.

Improving toxicology[4] and ecotoxicology testing—the study of chemical, biological or physical agents that can be harmful to humans and the environment—and improving the ability of tests, models and assessment methods to better predict product safety issues is an area of focus for the APVMA.

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

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

- consider the appropriateness/adequacy of current risk assessment tools to fulfil its regulatory role of evaluating novel pesticides and veterinary medicines
- regularly investigate new risk assessment approaches to see if the regulatory science methods used 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 has been reached.

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

In 2015, a guidance document or 'roadmap' for conducting insect pollinator risk assessments was developed by the APVMA for its own use and for its environmental advisory agency and external advisors. The roadmap primarily draws upon a North American risk assessment document for pollinators published in 2014 but uses additional information provided in a 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.

[4] This includes the development of new methods to reduce or replace animals in toxicology testing as well as to refine existing tests—the Three Rs.

Case study—genomic recombination

Prior to 2007, for more than 40 years, 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 per cent 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 Monitoring and enhancing regulatory science performance

The APVMA conducts its work according to the APVMA Standard on good regulatory science. There are a number of processes and procedures in place to ensure the integrity of regulatory decision-making. The organisational structure of the APVMA technical teams provides peer-review capability for assessment drafts on human health, environmental, residues, chemistry, and efficacy that were prepared by our advisory agencies, by external consultants and by APVMA staff.

Participation in international workshare arrangements with overseas regulatory agencies also introduces a peer-review element into the APVMA's evaluations and provides a yardstick to measure the quality of risk assessments.

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

To help monitor and improve performance, the APVMA will:

- use its Science Quality Committee (SQC) to consider and address issues related to the quality of scientific processes and regulatory outputs
- ensure the APVMA risk assessments of particular chemical products or product types are proportionate to the likely risks posed, by implementing a framework which takes into account the fact that not all products pose the same level of regulatory concern and therefore do not require the same level of regulatory intervention
- increase our use of international data, assessments, standards and decisions
- improve the availability of technical guidance materials which explain how the APVMA uses information and valid scientific argument to ensure the statutory criteria can be satisfied.

Risk assessments are conducted for new agvet chemicals and products to ensure they are appropriately peer-reviewed. Regulatory scientists at the APVMA also have a role in providing relevant advice to policy makers who are responsible for shaping the regulatory framework within which risk assessments are performed and decisions made. A scientific approach is essential to the analysis of available data and information to enable evidence-based policy development. A rational regulatory framework will help to improve the quality of risk assessment and risk management.

Case study—establishing the Office of the Chief Scientist within the APVMA

In late 2014 the APVMA established the Office of the Chief Scientist to help ensure the APVMA 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. The Office also:

- develops appropriate projects and initiatives to improve the organisation's scientific capability and performance
- provides the Chief Executive Officer and senior staff direct access to independent, expert advice on regulatory decisions
- provides the Chief Executive Officer and senior staff with scientific expertise concerning the APVMA's regulatory framework.