Government response to the final report of the independent review of the pesticides and veterinary medicines regulatory system in Australia

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Department of Agriculture, Water and the Environment
GPO Box 858 Canberra ACT 2601
Telephone 1800 900 090
Web awe.gov.au

Acknowledgements

The authors thank all parties consulted for their input.

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Introduction

The Australian Government welcomes the final report of the independent review of the pesticides and veterinary medicines regulatory system in Australia. The government thanks the independent review chair and panel for their work, Mr Ken Matthews AO, Dr Anne Astin AM PSM, Dr Mary Corbett and Dr Craig Suann.

The review

The independent panel was appointed by the then government on 5 September 2019. The review examined the pesticides and veterinary medicines regulatory system's aims, structure and operation, and made recommendations to ensure that it is contemporary, fit for purpose and reduces unnecessary red tape.

The panel released its issues paper on 4 March 2020 and undertook targeted consultation from March to June 2020. The draft report was then published on 16 December 2020. The draft report contained 139 recommendations and was open for consultation from 16 December 2020 to 26 February 2021.

The government recognises the extensive consultation undertaken during the review and the level of consideration afforded to stakeholder submissions by panel members. The panel received 100 written submissions on its issues paper, and 72 written submissions on its draft report.

The panel consulted with over 200 stakeholders and received 170 written submissions throughout the various stages of the review.

The panel heard from:

- government bodies
- grower groups
- chemical companies
- industry groups
- non-government organisations
- individuals and communities.

The panel submitted its final report to the then Minister for Agriculture and Northern Australia, the Hon David Littleproud MP, on 28 May 2021 and was subsequently published on 2 July 2021. The report contains a total of 58 recommendations, many of which were carried over from the draft report and/or amended as a result of public submissions.

The key findings of the final report are:

- the APVMA is a world class regulator
- opportunities exist to reduce red tape and improve efficiency by improving alignment with international regulators

- science and safety must remain at the centre of any proposed changes to ensure the integrity and confidence in the regulatory system
- Australian farmers do not have the same access to chemicals as their international competitors and improvements to chemical access are required
- the current regulatory system is not equipped to manage emerging technologies
- improvements can be made that will contribute to Australia's preparedness against highly emergent pests and diseases
- the current regulatory system is inefficient, outdated and largely without change since its inception in the early 1990s.

The current regulatory system

Responsibility for the current regulatory system is shared between the Commonwealth and state and territory governments. The Australian Pesticides and Veterinary Medicines Authority (APVMA) is the independent statutory authority responsible for assessing and registering pesticides and veterinary medicines proposed for supply in Australia. State and territory governments are responsible for controlling the use of pesticides and veterinary medicines beyond the point of retail sale.

The pesticides and veterinary medicines framework has been subject to numerous reviews since its establishment in 1993, none of which were based on a first principles approach. The panel's independent review provided an opportunity to propose fundamental changes throughout the regulatory system with the aim of improved safety and access to pesticides and veterinary medicines.

The government response

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Australian Government response

Chapter 1

Recommendation 1

The Panel recommends the following vision be adopted as the object of the legislation for the future pesticides and veterinary medicines regulatory system:

"A trusted and nationally consistent regulatory system for the responsible and safe use of effective pesticides and veterinary medicines that enhances and protects the health of humans, animals, plants, and ecosystems while improving access to new products and uses."

s. 47C(1); s. 47E(d)

Recommendation 2

The Panel recommends that the future pesticides and veterinary medicines regulatory system is guided by the following 6 equally weighted objectives:

- protect human health and wellbeing
- protect animal health and welfare
- protect the environment
- support primary industries
- protect Australia's trade
- contribute to biosecurity preparedness.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 3

The Panel recommends that the following principles should govern the design and implementation of the new regulatory system:

- The regulatory system should be based on risk, not on hazard alone.
- Processes and decisions should be objective, independent and science-based.
- Regulatory decisions should be transparent, and decision-makers should be responsive to all stakeholders, including the community, users, and the regulated industry.
- Risk management measures should be reviewed as new information becomes available.
- The system should be efficient, and outcomes focused by making use of streamlined and fit-for-purpose regulatory practices.
- The system should achieve a single nationally consistent model with shared responsibility for managing the risks associated with the manufacture, import, export, supply, use, and disposal for regulated products.
- The system should be adaptive to new technologies, practices, and knowledge.
- The regulatory system should support a resilient supply chain.

s. 47C(1); s. 47E(d)

Chapter 2

Recommendation 4

The Panel recommends that the Australian Government works with states and territories, in the first instance, to implement a single national applied law approach to control-of-use regulation. If agreement cannot be reached with the states and territories within 12 months, the Commonwealth should use its constitutional reach to implement a single national law approach.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 5

The Panel recommends that the Department of Agriculture, Water and the Environment have responsibility for policy and legislation for control-of-use as well as associated licensing activities. The Panel also recommends that 'on the ground' control-of-use functions continue to be delivered by the states and territories, but now with the national guidelines, with increased resources made available through the Commonwealth providing an additional $5 million per annum conditional funding across all states and territories.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 6

The Panel recommends that the need for, and the scope, role, and form of a new Intergovernmental Agreement (IGA) are considered as part of this review's implementation. The Panel also recommends the existing IGA be extended until a new IGA is formed.

Any future IGA should:

- provide that where consensus on a common approach cannot be reached, a majority (e.g., two-thirds) agreement by jurisdictions will prevail
- require any jurisdiction that departs from the IGA approach to provide a public reason for such departure
- mandate minimum resource levels for regulating control-of-use compliance and enforcement activities, to effectively meet assurance obligations and require publication of those resource levels
- require regular input by each jurisdiction for the purpose of public reporting against performance indicators for the entire regulatory system, supported by clear targets or goals
- require regular publication (or input to the Department of Agriculture, Water and the Environment's reporting) of performance against these indicators and targets or goals.

s. 47C(1); s. 47E(d)

Recommendation 7

The Panel recommends the establishment of a position in the Department of Agriculture, Water and the Environment to be known as the Commissioner for Pesticides and Veterinary Medicines. The Commissioner will have responsibility for:

- strong and independent policy leadership and responsibility to recommend and drive continuous improvement
- reporting on whole-of-system impacts and outcomes through biennial reports based on whole-of-system performance measures
- whole-of-system surveillance and monitoring, drawing on data from a range of sources
- ongoing open engagement with stakeholders
- establishing and leading Stakeholder and Whole of System Forums

- establishing a domestic produce monitoring program.

s. 47C(1); s. 47E(d)

Recommendation 8

The Panel recommends that the Commissioner advise Government and the public on the performance of the regulatory system as a whole by establishing a set of comprehensive performance measures that cover the entire regulatory system. The Commissioner should also establish health-risk indicators for Australia.

The Commissioner would be responsible for producing a biennial report of whole-of-system performance and make this report publicly available. The Commissioner should report publicly on the progress of the reforms in its first year, with system wide reporting on performance measures commencing 2 years from commencement of implementation of the proposed system reforms to allow a reasonable transition period for measuring impact.

Reporting should be informative and educational and include the results of domestic produce residue monitoring and environmental monitoring as well as adverse experience reports, providing the community with assurance that pesticides and veterinary medicines are being used safely, or in cases of exceedances, that response action is being taken. The data must be de-identified and privacy concerns must be addressed prior to publishing, consistent with the Australian Privacy Principles.

s. 47C(1); s. 47E(d)

Recommendation 9

The Panel recommends the establishment of a 5 member, skills-based board (including the CEO of the APVMA as an *ex officio* member) for the APVMA to strengthen its governance arrangements, provide the necessary oversight to support it in managing operational, financial and performance matters, and drive the reform agenda.

s. 47C(1); s. 47E(d)

Recommendation 10

The Panel recommends that the Commissioner have responsibility for convening and hosting 2 formal and one ad-hoc consultation mechanisms to consider and offer advice to ministers and the Department of Agriculture, Water and the Environment on the impacts and other consequences of policies, laws and other initiatives that affect, or are affected by, the use of pesticide and veterinary medicine products. These mechanisms are:

- a Stakeholder Forum
- a Whole of System Forum
- Expert Advisory Panels (as needed).

Terms of reference should be consistent with those set out in Annex 10 and Annex 11.

s. 47C(1); s. 47E(d)

Chapter 3

Recommendation 11

The Panel recommends that the Commissioner develop a cost-effective, integrated national data surveillance system fit for the needs of a 30-year future. The Commissioner should also develop arrangements to curate relevant information to enhance data accessibility and usefulness for research, policy formulation, public transparency, international reporting obligations, and

system response purposes. The Commissioner's biennial report should report on trends identified in system surveillance data.

The surveillance system should:

- Collate and analyse information from multiple data sources which may include annual pesticides and veterinary medicines sales and volume data, industry quality assurance programs, users' records, published literature, changes in market expectations, decisions by overseas regulators, and intelligence or reports from professional bodies and academic institutions.
- Incorporate residue detections from monitoring of domestic produce, environmental monitoring data and adverse experience reports to support a more comprehensive surveillance system.

s. 47C(1); s. 47E(d)

Recommendation 12

The Panel recommends increased whole-of-system monitoring by government of pesticides and veterinary medicines in produce and the environment.

Domestic produce monitoring

- Establishment of a comprehensive, cost-effective, and authoritative Government-led national domestic produce monitoring system. The scheme should build on and extend the current National Residue Survey infrastructure, which would leverage existing processes for sample collections, laboratory analysis and result reporting, as well as staff expertise.
- A domestic produce monitoring program with multi-year sampling priorities determined in consultation with the National Residue Survey, primary producers, the community and state and territory governments to ensure it aligns with the whole-of-system surveillance scheme.

Water and soil monitoring

- Monitoring water, waterway sediment and soil samples to detect levels of pesticides, parasiticides and antimicrobial drugs in the environment. The testing program should be scalable and targeted, based on risk.

- Residue soil testing should be incorporated into any soil monitoring program established under the National Soil Strategy

Environmental monitoring

- Development of a government funded, risk based, Environmental Monitoring Plan to identify areas of priority for monitoring taking account of the 13 major water catchments and key agricultural zones (for soils) across Australia. Further, the Panel recommends the collection and testing of samples be done on a seasonal basis to take account of differing cropping, weather patterns and pesticide patterns.

s. 47C(1); s. 47E(d)

Recommendation 13

The Panel recommends that adverse experience reporting be consolidated, improved, and better utilised:

- The structure and reporting process required when reporting adverse experiences should be detailed in legislation for both pesticides and veterinary medicines.
- The Department of Agriculture, Water and the Environment develops and maintains a single national portal for adverse experience reporting under the single national law for control-of-use. The Department of Agriculture, Water and the Environment should collate reports to establish a system wide 'pharmacovigilance' approach.
- The national adverse experience reporting portal would automatically refer reports to the appropriate authority when they are received, thus acting as a single point of contact and automated report referral system, while also providing for a national database of adverse experiences.

- The APVMA and state and territory regulators would be provided with tailored access to the adverse experience report dataset and should publicly report on adverse experience reports that fall under their jurisdiction.

s. 47C(1); s. 47E(d)

Recommendation 14

The Panel recommends the transparency and responsiveness of the chemical review process be improved. Reviews should be initiated through one of 3 mechanisms: as the result of a well-defined, legislated trigger (such as a relevant international decision); at the discretion of the APVMA; or on referral from the Commissioner.

If the APVMA is required to commence a review into substances on the basis of the trigger, it would be required to publicly disclose that the review is commencing. However, the trigger should not result in repeated near identical reviews within a 3-year period, unless APVMA chooses to initiate a review within this time.

Where an international decision would trigger a chemical review, but the APVMA considers the matter is not relevant to the Australian circumstance, the APVMA would not be required to carry out the review. However, in such a case the APVMA would be required to publish, within 6 months of the trigger occurring, a statement of reasons for not conducting the review.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 15

The Panel recommends the Commissioner have responsibility for referring substances to the APVMA for review where issues have been identified through its system-wide surveillance program. Similarly, the Commissioner should be able to refer substances imported under the international licensing scheme to the Department of Agriculture, Water and the Environment for investigation.

To refer a chemical to the APVMA or Department, the Commissioner would need to be satisfied that there are sufficient reasons to consider a review and would need to provide those reasons to the APVMA or Department when making the referral.

If the APVMA or Department chooses not to initiate a chemical review or investigation based on a referral from the Commissioner, it should be required to publish a statement of reasons for not conducting the chemical review or investigation within 3 months of the referral being made.

s. 47C(1); s. 47E(d)

Recommendation 16

The Panel recommends that the chemical review process rely on established suspension, cancellation, and variation administrative processes. This approach will streamline regulation and rely on processes established for other administrative actions by the APVMA.

s. 47C(1); s. 47E(d)

Recommendation 17

The Panel recommends that a humaneness score for vertebrate pest control products, based on the model developed and used by the NSW DPI Vertebrate Pest Research Unit, and adopted by

the Australian Animal Welfare Strategy, be presented on the label so that users can make an informed decision regarding the humaneness of a vertebrate pest control product.

s. 47C(1); s. 47E(d)

Chapter 4

Recommendation 18

The Panel recommends (concurrent with the recommendations for achieving nationally consistent control-of-use) that general product obligations should apply to dealings with pesticides and veterinary medicines to formalise and acknowledge responsibilities of all users across the life cycle of a product from design to disposal. These should enhance current existing industry processes, including codes of practice, work health and safety risk management plans, spray diaries, animal treatment records, industry QA, and stewardship schemes and be consistent with existing management practices to minimise the regulatory burden in meeting these obligations.

The general product obligations should be performance based, preventative, tailored, integrated and consistent, and apply to the life cycle of pesticides and veterinary medicine products. The expectations that apply to general product obligations shall be limited to what is reasonably practicable for the particular obligation holder to avoid harm to health, safety and trade, and actions to demonstrate compliance through suitable analysis, systems and record keeping (Annex 7 provides suggested example obligations).

s. 47C(1); s. 47E(d)

Recommendation 19

The Panel recommends the Department of Agriculture, Water and the Environment develop a single national legislative framework to accommodate all licences, throughout the product life cycle. The single national licensing framework should enable specific, targeted licensing schemes to be created to regulate specific activities irrespective of whether they relate to supply or use activities. All licences for individual schemes created under the national licensing framework would, with the exception of good manufacturing practice and hormonal growth promotant licensing, be issued by the Department of Agriculture, Water and the Environment, who would also have responsibility for compliance and enforcement activities associated with activities conducted under a licence. Licences should be issued to businesses where possible, rather than individuals, with businesses responsible for undertaking due diligence to ensure their operators hold the accredited education, training, competencies, or other relevant qualifications.

Such licences, where relevant, would incorporate mandatory licence conditions that allow for the recognition of suitably rigorous industry quality assurance schemes.

s. 47C(1); s. 47E(d)

Recommendation 20

The Panel recommends that all businesses who apply pesticides commercially (be it agricultural or domestic) are responsible for ensuring operators complete accredited education, training, competencies or other relevant qualifications in chemical use and application techniques, including handling, storage, risk assessment and management, end-of-life cycle disposal and recycling, regardless of whether the activity is subject to licensing.

s. 47C(1); s. 47E(d)

Recommendation 21

The Panel recommends that the Department of Agriculture, Water and the Environment completes the work of HACCUT to establish suitably rigorous training standards for restricted chemical products and Schedule 7 poisons and builds on it to develop a comprehensive set of publicly available national training and competency standards for dealing with pesticides. Competency standards should be established for roles introduced through other recommendations in this review, including the issuing of special use licences.

These include:

- accredited assessors who undertake third-party assessment work for the APVMA (see Chapter 6)
- government auditors engaged to ensuring compliance with licensing requirements under veterinary manufacturing standards, (see Chapter 6), access to internationally registered products (see Chapter 5) and other nationally consistent licensing schemes.

Where similar industry-based accreditations or other qualifications exist or are developed, these may also be recognised as meeting the requirements for the qualification or licence, subject to review by the Department of Agriculture, Water and the Environment.

The Department of Agriculture, Water and the Environment. should also establish standing liaison arrangements with the Australian Skills Quality Authority and industry associations responsible for industry-based accreditations.

s. 47C(1); s. 47E(d)

Recommendation 22

The Panel recommends the Department of Agriculture, Water and the Environment, in consultation with relevant stakeholders and consistent with other standard setting approaches, establish the labelling standard under the single national law framework.

s. 47C(1); s. 47E(d)

Recommendation 23

The Panel recommends essential information that relates to safety, first aid, disposal, or use restrictions remain affixed to the product container, but that consideration is given to how it could be enhanced through more comprehensive smart label content.

s. 47C(1); s. 47E(d)

Recommendation 24

The Panel recommends that legislation to facilitate the use of smart labelling and machine-readable labelling be developed. The legislation should allow for progressive implementation of these technologies as telecommunication connectivity improves. Further, labels should not be prevented from including access to complementary and supporting electronic resources (such as links to a copy of the label, safety data sheet, instructional videos, educational material, and label instructions presented visually or in alternate languages).

s. 47C(1); s. 47E(d)

Recommendation 25

The Panel recommends that the label content, i.e., the information constituting the label for control-of-use matters, is divided into 2 categories: regulatory assessed elements (RAEs) and conditional required elements (CREs). The Panel recommends that CREs be those elements that are fixed and do not change as a result of assessment and would not form part of the APVMA's pre-market assessment. CREs would be required to be included on the label by product registration conditions and therefore be subject to post-market compliance. RAEs would then represent those elements for which the expert pre-market consideration of the APVMA is required. RAEs may be communicated, to the extent provided by the labelling standard, through means other than being affixed to the container.

s. 47C(1); s. 47E(d)

Recommendation 26

The Panel recommends that the APVMA, supported by legislation to the extent necessary, allows the inclusion of first aid and safety directions drawn from any Australian established standard to the extent they would ensure the safe handling of the product. The Panel considers this wording could, at the discretion of the applicant, be drawn from existing standards including APVMA first aid and safety directions, the Poisons Standard, or the Globally Harmonized System of Classification and Labelling of Chemicals (GHS).

s. 47C(1); s. 47E(d)

Recommendation 27

The Panel recommends manufacturers should be permitted (and indeed, should be encouraged) to include additional safety information on product labels, provided it is not inconsistent with the regulatory assessed label elements.

s. 47C(1); s. 47E(d)

Recommendation 28

The Panel recommends that every 5 years, at a minimum, the registration holder conducts its own review of label content to ensure the information on the label remains current and correct – noting that emerging scientific evidence or consumer concerns could also trigger review of the label at any time (see the chemical review discussion in Chapter 3).

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 29

The Panel recommends that when regulators are determining compliance with responsible stewardship and control-of-use requirements, they should only consider compliance with the regulatory assessed label elements and not against the content on the label not assessed by the APVMA.

s. 47C(1); s. 47E(d)

Recommendation 30

The Panel recommends strengthening good disposal practices (in line with good agricultural practice) by:

- encouraging industry quality assurance schemes to include requirements and guidance on good disposal practices as part of being deemed to meet general product obligations (see Section 4.1)
- responsible and sustainable disposal practices being considered as a condition for relevant licences
- publication of a list of companies importing or manufacturing pesticides in Australia that are not participating in the current voluntary industry programs or do not have equivalent programs in place, addressing container management, recycling, and disposal.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 31

The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with the prescription protocol. In developing the protocol, the Panel recommends:

- registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist
- the prescription protocol is finalised and implemented under the single national law for control-of-use
- the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.

Clarification

The first paragraph of the recommendation in the final report contained an error. The correct wording is below:

The Panel recommends that compounded veterinary products fall within the scope of the future regulatory system but are exempt from registration where they comply with a good compounding practice standard.

Additionally, the Panel recommends that veterinarians who prescribe compounded products, or other non-assessed or unapproved veterinary medicines, be required to comply with the prescription protocol. In developing the protocol, the Panel recommends:

- registered products be considered first, and compounded products are only prescribed where no suitable or available regulatory assessed products exist
- the prescription protocol is finalised and implemented under the single national law for control-of-use
- the APVMA works with the Australian Veterinary Association, Pharmacy Board of Australia and leading veterinary compounding pharmacies to ensure one or more suitable manufacturing standards are established to enable said exemption.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 32

The Panel recommends that an exemption to the requirement for licensing the production facility should be granted where the facility complies with a good compounding practice standard for veterinary medicines, and there is an arrangement for the reporting of adverse experiences.

s. 47C(1); s. 47E(d)

Recommendation 33

The Panel recommends establishing a national rule under the single national law for control-of-use that sets out the requirements for:

- a pesticide product's responsible use, including off-label use, and the records that must be kept establishing responsible use
- a veterinary medicine's responsible use, including a prescription protocol that applies to all animal use, and the records that must be kept establishing responsible use.

s. 47C(1); s. 47E(d)

Chapter 5

Recommendation 34

The Panel recommends efficiencies for the future regulatory system including:

- new definitions for pesticides and veterinary medicines that exclude product classes or uses that are expected to be low risk as they have low hazard or low exposure or are effectively and suitably regulated by other regulators (as outlined in Annex 5)
- establishment of exemption pathways which remove pre-market regulation for certain low regulatory concern products
- development of standards by the Department of Agriculture, Water and the Environment enabling the exemption pathways, utilising input from industry and public consultation

- establishment of a Products Requiring Pre-market Assessment (PRPA) list.

s. 47C(1); s. 47E(d)

Recommendation 35

In the case of pesticides or veterinary medicines that contain genetically modified organisms, the Panel recommends a system where one regulator (the APVMA or the Office of the Gene Technology Regulator (OGTR)) becomes the decision-maker for an application. Depending on the category of 'substance' and the risks it presents, it may be excluded from the scope of APVMA regulation. In other cases, the regulator making the decision could seek the other's advice when assessing an application and notify it, if and when the application is approved.

s. 47C(1); s. 47E(d)

Recommendation 36

The Panel recommends establishing a licensing scheme to allow for safe and effective pesticides and veterinary medicines registered by equivalent international regulatory systems but not available in Australia, to be supplied and used in Australia.

In support of this scheme, the Panel recommends:

- that there be an instrument setting out international regulators determined to be equivalent, and that this be regularly reviewed for currency

- that the Department of Agriculture, Water and the Environment, in consultation with the APVMA, determine equivalent regulators
- establishment of a list of prohibited chemistries and classes of products and uses that would not be allowed under licence
- that intellectual property protections for products supplied under licence be determined in consultation with industry during implementation.

The Panel recommends that licence holders:

- be required to make available all uses approved by an equivalent international regulator, except where the pest, disease, crop or animal is not present in Australia, or a specific grower/producer group only wants to bring in uses associated with their industry sector and within their control
- develop, submit for approval, and implement a risk management plan detailing practices for assessing and controlling risks associated with internationally registered products, with specific consideration of unique Australian circumstances
- be subject to regular audits to ensure they are complying with the approved risk management plan and other licence conditions
- be required to make risk management plans, with exceptions for confidential commercial information or other trade secrets, publicly available to ensure the community has confidence that the full range of risks have been identified and are being managed
- cannot supply a product under a licence arrangement where there is an equivalent Australian registered product while a data protection period is active provide information on request confirming the operation and adequacy of the licence holder's risk management and compliance with licence conditions.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 37

The Panel recommends expanding support by Government to the Improved Access to Agvet Chemicals Initiative, with a view to increasing industries' access to tools for pest and disease management.

s. 47C(1); s. 47E(d)

Recommendation 38

The Panel recommends establishing specific criteria to grant an emergency, research, or minor use permit, as long as the use of the product would not jeopardise safety or trade and is reasonably expected to be efficacious.

s. 47C(1); s. 47E(d)

Recommendation 39

The Panel recommends expanding the authorising of emergency use permits in advance of the emergency through establishing 2 categories within the public listing of permits for 'active-

emergency permits' and 'future-emergency permits'. Future-emergency permits would include details of the trigger to transition from the 'future' to 'active' permit category and vice versa.

s. 47C(1); s. 47E(d)

Recommendation 40

The Panel recommends building national research capacity through the adoption of a licensing scheme that authorises entities to undertake research relating to pesticides and veterinary medicines. The licence is to include a condition that a risk management plan has been approved, supported by research quality and safety management systems, and regular independent assurance checks including audits.

s. 47C(1); s. 47E(d)

Recommendation 41

The Panel recommends the APVMA be empowered to approve a priority need (use) via a supplemental label if it determines that further confirmatory data is necessary. Uses on the supplemental label will transfer to a permanent label following the provision and assessment of any confirmatory data, if and where required.

- Supplemental labels will not form part of the primary approved label attached to the product container, and will be approved for a fixed time only.
- The option to place a use on a supplemental label should be provided only for the priority pest, disease, and animal health needs identified by producers and veterinarians.
- The APVMA will identify the information necessary to confirm or refine the original decision as a condition of the supplemental label approval.
- A workplan will be a required condition to ensure delivery of the required information before expiration of the supplemental label.

s. 47C(1); s. 47E(d)

s. 47C(1); s. 47E(d)

Recommendation 42

The Panel recommends:

- a 'fast track' application process for pesticides and veterinary medicines that meet prescribed criteria (including, but not only, introduction of a new active constituent, use on a crop group, alternatives to chemicals under review, specialised areas classed as minor uses, reduced environmental risks, increased environmental benefits, or controlling pest, weeds or diseases of national significance) to improve access in response to priority needs.
- criteria for prioritisation be drafted by the Department of Agriculture, Water and the Environment, and determined by the Minister.

s. 47C(1); s. 47E(d)

Recommendation 43

The Panel recommends:

- the APVMA provide nationally consistent use patterns for pesticides and veterinary medicines as the default arrangement with targeted controls implemented only where warranted
- targeted controls be based primarily on climatic regions, with other regional divisions able to be used where the risk factors to be managed do not align with climatic regions.

s. 47C(1); s. 47E(d)

Recommendation 44

The Panel recommends amendments to the Biosecurity (Conditionally Non-prohibited Goods) Determination 2021 to expand alternative conditions for imports of biological pesticides and veterinary medicines. The Panel also recommends the overall pesticides and veterinary medicines regulatory system performance indicators include measuring biologically-based products by quantifying their number and growth over time.

s. 47C(1); s. 47E(d)

Recommendation 45

The Panel recommends that the APVMA must consider national benefits and the consequences of not having access to a product when proposing to either refuse an application for registration, or to suspend or cancel a registration for reasons other than as an administrative sanction.

s. 47C(1); s. 47E(d)

Recommendation 46

The Panel recommends that the limits on the regulator's use of information should be the minimum needed to encourage new uses or chemicals without needlessly impeding flow-on innovation, competition, and access to alternative chemical products.

- Equivalent protection periods should be provided for pesticides and veterinary medicines.
  - 10 years for registration of a new product with a new active constituent or approval of a new active constituent
  - 5 years for information relied on by the regulator to vary an active constituent, register or vary pesticides or veterinary medicines containing an existing active constituent, issue a research permit, provided in support of a chemical review, or where information contradicts information in the Record or Register.

- The same arrangements should apply irrespective of how the information has been provided to the regulator (e.g., associated with a registration application or a chemical review).
- These periods should only be further extended as an incentive to bringing priority uses to Australia, as per the measure in the Agricultural and Veterinary Chemicals Legislation Amendment (Australian Pesticides and Veterinary Medicines Authority Board and Other Improvements) Bill 2019 currently before Parliament.
- These limitation periods should not prevent the regulator using information where there is a public interest reason to do so.

s. 47C(1); s. 47E(d)

Recommendation 47

The Panel recommends discontinuing the APVMA's role in arbitrating data access and compensation agreements between parties with similar products and uses that are under review. Negotiation of data access and compensation is best left as a matter to negotiate between companies.

s. 47C(1); s. 47E(d)

Chapter 6

Recommendation 48

The Panel recommends active constituents be considered and approved at a 'substance level', independent of site of manufacture. The APVMA should:

- establish a standard for each active constituent prior to its inclusion in products

- ensure due regard is given to matters of commercial confidentiality and intellectual property protection in development of these standards
- apply measures to retain access to necessary information establishing the source of the material and its compliance with the relevant standard including in products.

s. 47C(1); s. 47E(d)

Recommendation 49

The Panel recommends the establishment, within 18-months of an open and transparent pre-application third-party assessment process to expand the skills base in Australia for assessments beyond the APVMA. The model for this scheme should be based on the model that was previously included in the lapsed Agricultural and Veterinary Chemicals Legislation Amendment (Streamlining Regulation) Bill 2018.

s. 47C(1); s. 47E(d)

Chapter 7

Recommendation 50

The Panel recommends changes to the existing levy on product sales including:

- that the levy be continued but at a reduced rate with each component of the levy being charged only to those that receive the corresponding service
- where regulatory effort for an activity reflects the volume or value of products sold, the component of the levy should be based on a volume or value of product sales and may be tiered. In other cases, the component of the levy should ideally be a flat charge.

s. 47C(1); s. 47E(d)

Recommendation 51

The Panel recommends changes to assessment charging structures including:

- the introduction of hourly charging for highly variable regulatory activities and flat rates for activities with little variation
- that the costs for registration applications be 100% recovered directly from applicants through an assessment fee, charged on an hourly basis
- the assessment of applications for accreditation, together with the costs to maintain this accreditation, be 100% recovered from the accredited parties
- that the full costs for advice given by the APVMA in relation to an application for registration should be recovered, by fees, charged on an hourly basis, with the first hour's advice provided 'free of charge'.

Recommendation 52

The Panel recommends 100% cost recovery for issuing and maintaining licences via application fees. Flat fees should be charged where there is little variation, and hourly charging for activities where regulatory costs are highly variable.

Recommendation 53

The Panel recommends that where Government audits are routine and predictable the costs of this service be incorporated into the fees for the parent program for example, via licence fees. Where the cost of the audit is highly variable, for example veterinary medicines manufacturing audits, the cost should be recovered on a full hourly fee-for-service basis.

Recommendation 54

The Panel recommends changes to the APVMA's permit charging structure including:

- maintaining a substantial level of subsidisation for applications to access minor and emergency uses of pesticides and veterinary medicines
- minor use permit applications should attract a discounted application fee with the balance of costs recovered via the levy on product sales payable by the holder

- emergency use permit applications should be fully recovered as a component of the levy.

Recommendation 55

The Panel recommends that the costs of chemical reviews and APVMA compliance and enforcement activities be recovered entirely from industry via a component of the levy on product sales.

s. 47C(1); s. 47E(d)

Recommendation 56

The Panel recommends that the cost of general control-of-use compliance and enforcement activities should continue to be funded by states and territories under their current funding arrangements. However, wherever possible or, where the beneficiary is clearly identifiable, such as a licensed operator, a fee-for-service approach would be used. The Panel also recommends an additional Commonwealth Government contribution of $5 million per annum to support the increase in post market compliance and enforcement activities.

s. 47C(1); s. 47E(d)

Recommendation 57

The Panel recommends public funding for the costs of:

- data mining and analysis for system surveillance and monitoring
- environmental monitoring
- domestic produce monitoring.

s. 47C(1); s. 47E(d)

Recommendation 58

The Panel recommends that the activities of the Commissioner such as reporting on progress in the transformation process, system surveillance and monitoring, and the cost of stakeholder consultation should be Government funded.

s. 47C(1); s. 47E(d)

Annex 1: Consultation on the government response

The Department of Agriculture, Water and the Environment undertook broad consultation during development of the government response. Commonwealth and state and territory agencies, including the APVMA, and targeted stakeholders and individuals participated in consultations.

Commonwealth interdepartmental committee

The department established a Commonwealth IDC to ensure that relevant Commonwealth entities were engaged and invited to share their views on the panel's recommendations. The Commonwealth IDC included members from the following Australian Government departments:

- Department of the Prime Minister and Cabinet
- The Attorney-General's Department
- Department of Health
- Department of Agriculture, Water and the Environment
- The Treasury (observer)
- Department of Finance (observer)

Members represented their department, and any relevant portfolio agencies (APVMA, TGA, FSANZ, AICIS, ACCC, and OGTR). The Commonwealth IDC met 3 times throughout the consultation process.

State and territory interdepartmental committee

A state and territory IDC was established to ensure that relevant state and territory government entities were engaged and invited to share their views on the panel's recommendations, particularly the proposed establishment of a single national law for control-of-use. The state and territory IDC included members from the following jurisdictional departments:

- ACT Environment, Planning and Sustainable Development Directorate
- NSW Department of Primary Industries
- Primary Industries and Regions SA
- Tas Department of Primary Industries, Parks, Water and Environment
- NT Department of Industry, Tourism and Trade
- Vic Department of Jobs, Precincts and Regions
- Qld Department of Agriculture and Fisheries
- WA Department of Primary Industries and Regional Development

Members represented their department and wider jurisdiction. The state and territory IDC met 4 times throughout the consultation process and the department continues to engage with jurisdictions post-consultation.

Targeted stakeholder consultation

Over 25 stakeholder groups were consulted, including:

- grower groups
- chemical companies
- industry groups
- non-government organisations
- individuals and communities.

Participants' views on the proposed reforms were sought and these views were considered while preparing the government response.