

Chapter 5

Transparency and community consultation

5.1 The importance of transparency and the need to maintain the confidence of the communities they serve are fundamental to the operations of the APVMA and regulators across the world. This inquiry has identified a number of issues that the APVMA must address if it is to maintain a strong level of community confidence in its decisions.

5.2 Many submitters to the inquiry expressed concern about the operations of the APVMA, including the regulator's priorities, processes, independence and responsiveness. Concerns were also raised about the availability of data and evidence, and the dangers of glyphosate and a range of other chemicals.¹ The lack of confidence in the work of the regulator expressed in evidence to the committee was affirmed in a 2018 survey of the APVMA which found that only 62 per cent of respondents held the view that the regulator's decisions were underpinned by science.²

5.3 While considerable evidence to the committee raised concerns about the APVMA's decisions, the inquiry has revealed that it is the manner in which decisions are communicated, rather than the scientific soundness of the decisions themselves, that requires improvement. Furthermore, there would appear to be considerable scope for the APVMA to improve its community consultation processes in order to better understand and respond to community concerns. Implementation of a community consultation mechanism would also assist the regulator in combating some of the community's concerns about its independence and assist in demystifying its decisions for the general public.

Confidence in the regulator and industry social licence

5.4 It became clear to the Committee that stakeholders who had active and regular engagement with the APVMA were more likely to have confidence in its scientific rigour and independence; whilst organisations and individuals who did not have direct or regular contact with the authority tended to question its impartiality, processes and evaluations.

5.5 For instance, Cotton Australia, which regularly engages with the APVMA, stated:

1 See, for instance: H Ross, *Submission 28*; Mrs Lara Warwick, *Submission 29*; Ms Jessica Harrison, *Submission 37*; Mr Chris Anderson, *Submission 38*; Ms Alison Wylie, *Submission 39*; Gene Ethics, *Submission 40*; Ms Kali Moynihan, *Submission 43*; Mr Andrew Zimmerman, *Submission 66*; Ms Svyetlana Hadgraft, *Submission 69*; Mr Neal Salan, *Submission 74*; Sustainable Agriculture & Communities Alliance, *Submission 76*; Mr Richard Nankin, *Submission 77*; Ms Patsy Lisle, *Submission 92*; Ms Vanda Grabowski, *Submission 93*; Ms Sarah Toose, *Submission 98*; Joint Submission, *Submission 103*; Pesticide Action Group WA, *Submission 104*; Alliance for a Clean Environment, *Submission 105*.

2 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, p. 32.

The safety of agricultural chemicals for users, communities, consumers and the environment must be of the highest priority. Regulatory decisions must be made independently, using rigorous scientific methods, to ensure the safety of the community, animals and the environment. The APVMA is globally recognised as a world leading regulator that makes decisions based on science.³

5.6 As discussed in previous chapters, this view was widely held across the agricultural and veterinary medicines industries. At the same time there was recognition that this was not sufficient. It was agreed that the agriculture industry also required a social licence, particularly in the context of greater consumer advocacy and sometimes negative representations of farming and chemical use.⁴

5.7 A representative of both the National Farmers' Federation and NSW Farmers' Association informed the Committee:

We are now as organisations and as a farming community very aware of our...social licence to operate, because so many people are watching everything we do. We are covering everything, making sure that, as much as possible, it is acceptable. I also have a fair bit to do with agripolitics and animal welfare, and something we are looking at there is the fact that it has to be socially acceptable, and chemical usage definitely comes under that. We have to make sure that what we are doing is socially acceptable to the community.⁵

5.8 Those organisations and individuals who voiced a lack of confidence in the APVMA were equally suspicious of the chemical industry and raised concerns about the relationship between the two. As a case in point, Ms Immig from the National Toxics Network expressed the view that:

The ag and vet chemical lobby are extremely powerful and they are getting exactly what they want, while the community and the environment pay the price for continued registration and use of dangerous pesticides.⁶

5.9 Friends of the Earth Australia told the Committee that 'time and time again in history, there are chemicals that are regarded as safe and then, five or ten years later, scientists will find somewhere that they're not safe at all'.⁷

5.10 Focusing on the glyphosate matter, Dr Musgrave explained the lack of trust some within the broader community had in the APVMA:

3 Cotton Australia, *Submission 6*, p. [1].

4 See, for instance: NSW Farmers' Association, *Committee Hansard*, 20 November 2018, pp. 20–22.

5 Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation; Vice President, NSW Farmers' Association, *Committee Hansard*, 20 November 2018, p. 16.

6 Ms Joanna Immig, National Toxics Network Inc, *Committee Hansard*, 7 December 2018, p. 25.

7 Mr Anthony Amis, Pesticides and Drinking Water Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

The subject of glyphosate is particularly emotive, the potential for wide ranging entry of this chemical into the ecosystem (despite evidence that glyphosate residues on Australian crops are negligible), the emotive association glyphosate with Genetically Modified crops and Monsanto (despite glyphosate being off patent and being manufactured by many other companies now), misunderstanding of the amounts consumers are exposed to and the confusion of Australian versus US farming practices makes it difficult for consumers to feel they have trust in regulatory agencies. A similar emotive issue arose recently with the relatively safe insecticide pyriproxyfen. Issues such as lack of autonomy in decision making and perceived lack of transparency in information exchange contribute to this lack of trust.

Events such as the recent Californian court case suggest to consumers that their regulatory agencies are compromised, regardless of the actual facts... Regaining this trust will require substantial effort, and the lessons around vaccine hesitancy may be relevant here where public trust is eroded despite significant evidence of benefit and minimal harm.⁸

5.11 To address concerns about transparency and to meet legislative requirements, the APVMA publishes application summaries, and information on manufacturing licences and approval or variation of an active constituent or registration. It also makes available information about its regulatory processes.⁹

5.12 Nevertheless, many organisations including the National Toxics Network explained that they were unable to discuss matters of concern directly with the APVMA. The issue of consultation and communication is considered later in this chapter.

Concerns raised about the APVMA

A potential conflict in the role of the APVMA

5.13 A number of submitters raised concerns about what they saw as an inherent conflict in the ability of the APVMA to protect community wellbeing whilst also furthering trade and commerce, and the viability of Australia's primary industries.

5.14 This issue was previously recognised by the Productivity Commission, which identified the multiple considerations and potential need for tradeoffs in the Agvet Code Act. The Agvet Code Act recognises, amongst a range of other things:

- a) that the protection of the health and safety of human beings, animals and the environment is essential to the well-being of society and can be enhanced by putting in place a system to regulate agricultural chemical products and veterinary chemical products; and

8 Dr Ian Musgrave, *Submission 41*, p. [4].

9 Australian Pesticides and Veterinary Medicines Authority, *Transparency*, <https://apvma.gov.au/node/267> (accessed 10 January 2019).

- b) that the principle of ecologically sustainable development requires a regulatory system that is designed to ensure that the use of such products today will not impair the prospects of future generations; and
- c) that the furthering of trade and commerce between Australia and places outside Australia, and the present and future economic viability and competitiveness of primary industry and of a domestic industry for manufacturing and formulating such products, are essential for the well-being of the economy and require a system for regulating such products that is cost-effective, efficient, predictable, adaptive and responsive...¹⁰

5.15 Some stakeholder groups suggested the APVMA was not taking human health and impacts on the environment into account when making assessments or decisions. Gene Ethics criticised what it perceived as the APVMA's priority 'to get new active ingredients onto farms'.¹¹ The Local Environmental Action Forum stated the safety of human and environmental health should be the APVMA's top priority.¹²

5.16 The National Toxics Network was also of the view that a better balance was required within the APVMA, arguing:

It's all about efficiency at the front end to get the products on to the market quickly, which is fair enough, but it consistently fails to review chemicals in a timely way and get them off the market when it's needed...The balance between safeguarding community and environmental health and agricultural productivity has been out of kilter for decades.¹³

Comprehensiveness of APVMA assessments

5.17 Two key issues were raised in evidence regarding the comprehensiveness of the regulator's assessments: the product-specific focus of APVMA assessments; and perceived shortcomings with the regulatory science approach.

5.18 Friends of the Earth Australia suggested APVMA assessments were incomplete:

At the assessment stage, the APVMA assesses only individual chemicals and not the combined, synergistic, cumulative and long term impacts on human health and the environment. In assessing the safety of chemicals, the APVMA does not assess the safety of whole formulations but solely so-called 'active ingredients'—despite the evidence that many 'inactive'

10 *Agricultural and Veterinary Chemicals Code Act 1994* (long title). See also: Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 204.

11 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 22.

12 Mr Marden Philip Hundley, Local Environmental Action Forum, *Committee Hansard*, 7 December 2018, p. 62.

13 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 25.

ingredients can have significant impacts on the nature and scale of the chemical's impacts.¹⁴

5.19 This view was supported by an earlier review of the APVMA's risk-assessment processes undertaken by the Australian Academy of Technological Sciences and Engineering that found (as reported by the Productivity Commission):

APVMA hazard and risk assessments are product specific and do not consider the cumulative and synergistic environmental and health effects of multiple chemicals. There is no routine assessment of multiple exposures or of all likely workplace mix combinations of pesticides. Further, there is no assessment of the cumulative or synergistic effects of multiple pesticide residues on human health, or on the environment.¹⁵

5.20 Gene Ethics also voiced its concerns over the APVMA's assessment processes, suggesting:

The APVMA's assessments are not scientific or objective as only the so-called active components of chemical formulations are the primary focus of assessment and regulation, yet many other ingredients can also pose substantial but unassessed hazards. APVMA assessments are also blind to the cumulative and synergistic impacts of multiple chemicals all approved on the same crops. For instance, a carrot may have up to 14 different approved chemicals sprayed on it, yet each of those chemicals is assessed and approved in isolation from all the others. The interaction of their residues in human and animal food supplies is also ignored.¹⁶

5.21 DAWR challenged these views, noting that under the National Residue Survey Program, it undertook monitoring of agvet chemical and environmental contaminant residues in food commodities and published the results of the annual survey. The survey involved random, targeted and compliance monitoring of agvet chemical residues and environmental contaminants in selected animal and plant products. The survey helped to identify compliance issues that may require follow-up action by regulators.¹⁷

5.22 Concerns about the scientific basis of the APVMA's assessments were often tied to questions about the appropriateness of regulatory science in assessing chemicals, and calls for the adoption of the precautionary principle.

5.23 In making a case for the precautionary principle, some submissions drew upon the APVMA's 2015 *Regulatory Science Strategy: Consultation Draft* definition of regulatory science. The draft definition stated:

What differentiates regulatory science from conventional [research] science is that decisions are based on analysis and interpretation of existing

14 Friends of the Earth Australia, *Submission 35*, p. [4].

15 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 207.

16 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 19.

17 Department of Agriculture and Water Resources, *Submission 9*, p. 6.

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.¹⁸

5.24 Gene Ethics, in particular, criticised this approach by suggesting it was 'passive and selective' and allowed applicants to submit unverified evidence in support of their claims of safety and efficacy and where gaps existed, allowed assumptions to be made.¹⁹

5.25 The APVMA pre-empted some of these criticisms in its consultation draft by confirming the broad expertise of regulatory scientists, stating:

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.²⁰

5.26 The APVMA released its final *Regulatory Science Strategy* in 2016, which detailed the scientific basis of the regulator's decisions and outlined six strategic initiatives to further strengthen its regulatory science expertise. The strategy also contained an updated definition of regulatory science:

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 or generated by research scientists and published in the peer-reviewed scientific literature to make a decision.²¹

5.27 Many criticisms of the APVMA's assessment processes were accompanied by a call for the authority to adopt the precautionary principle (to be distinguished from

18 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy: Consultation Draft*, November 2015, p. 3.

19 Gene Ethics, *Submission 40*, p. 18.

20 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy: Consultation Draft*, November 2015, p. 3.

21 Australian Pesticides and Veterinary Medicines Authority, *APVMA Regulatory Science Strategy*, August 2016, p. 4.

the APVMA's precautionary approach), which requires evidence to prove a chemical is safe, rather than relying upon the absence of evidence it is unsafe.²²

5.28 The Australian Food Sovereignty Alliance drew upon an example of the precautionary principle in practice in the *Environment Protection and Biodiversity Conservation Act 1999*, which provides a 'legal framework to protect and manage nationally and internationally important flora, fauna, ecological communities and heritage places'.²³ The Act's definition of the precautionary principle provides that:

...[a] lack of full scientific certainty should not be used as a reason for postponing a measure to prevent degradation of the environment where there are threats of serious or irreversible environmental damage.²⁴

5.29 Friends of Earth Australia also criticised the APVMA for not applying the precautionary principle:

In Europe, pesticides have to be proven safe to human health and the environment in order to be allowed onto the European market. It is the responsibility of industry to provide the data showing that a pesticide can be used safely. Australia does not have the same system as Europe and the APVMA does not apply the same precautionary approach.

The APVMA implicitly shifts from a safety first to a market first approach by conflating the notion that no evidence of harm is the same as evidence of safety...it means that intervention will only occur once 'sufficient' evidence is provided to justify intervention. This occurs rarely.²⁵

5.30 The Committee heard, however, that the APVMA can and does have the authority to request information from registrants where there are identified gaps in scientific information. It was suggested that in the reconsideration process, the APVMA constantly calls for new data.²⁶

Public availability of data and peer review

5.31 Several submissions were critical of the APVMA not making data publicly available for peer review and for relying upon industry funded science or

22 See, for example: Ms Ruth Weston, *Submission 4*, p. [1]; Local Environmental Action Forum, *Submission 14*, p. 1; Mr Duncan Mills, *Submission 20*, p. [1]; Ms Janet Grogan, *Submission 36*, p. [2]; Ms Kali Moynihan, *Submission 43*, p. [1]; Sustainable Agriculture & Communities Alliance, *Submission 76*, p. 2; Australian Food Sovereignty Alliance, *Submission 90*, p. 10; Pesticide Action Group WA, *Submission 104*, p. 5.

23 Australian Government Department of the Environment, *EPBC Act—Frequently Asked Questions*, http://www.environment.gov.au/system/files/resources/0de020d9-1c03-40d3-adb2-54710b97dbac/files/epbc-act-fact-sheet_2.pdf (accessed 4 January 2019).

24 *Environment Protection and Biodiversity Conservation Act 1999*, ss. 391(2).

25 Friends of the Earth Australia, *Submission 35*, p. [2].

26 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 49.

company-provided data as the basis for regulatory approval.²⁷ Friends of the Earth Australia, for example, commented:

The literature is now littered with examples of industry hiding data that shows evidence of harm and hiring compliant academics to produce evidence that suggests safety, such as with asbestos, tobacco and, we would argue, now, glyphosate as well.²⁸

5.32 However, it was put to the Committee that there was a conflict between making data publicly available for peer review, and protecting the proprietary information of companies. Bayer Crop Science contended:

I think the challenge there would be you have this problem that there's a reason a lot of the data and studies are held as proprietary. They can be used by anyone to register, and it's a considerable amount of resources to get those studies conducted.²⁹

5.33 However, Bayer Crop Science also acknowledged the need for publicly available peer reviewed studies; with the proviso there would be other studies not made publicly available for proprietary reasons, but they would be considered as part of risk assessments.³⁰

5.34 The Committee also heard support for current regulatory practices given that under such practices, companies were required to provide evidence that a substance was safe.³¹ Chemistry Australia stated:

The way the system works at the moment is that people who want to advance a position have to get independent research undertaken to prove and establish certain facts that prove that, when the product is used in accordance with the labelled directions, it doesn't present unacceptable risk to human health and to the environment.³²

Community consultations and responsiveness

5.35 Industry submitters and witnesses generally expressed satisfaction with the responsiveness of the authority, whereas other submitters and witnesses called for greater consultation and responsiveness to community concerns, including broader representation on the proposed APVMA board.

27 See, for example: Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 17; Mr Jeremy Tager, Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

28 Ms Louise Sales, Emerging Tech Project Coordinator, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 52.

29 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 5.

30 Dr William Reeves, Health and Safety Issues Manager, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 5.

31 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 45.

32 Mr Bernard Lee, Director, Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 50.

5.36 The views of the Veterinary Manufacturers and Distributors Association in this regard were broadly representative of industry perceptions:

Since its inception as a national regulator in 1994, the NRA, now APVMA, has monitored and engaged with industry to ensure that our production processes and capabilities and the scientific data that we supply to justify product registrations remain at the forefront of international standards for animal health products. In return, we hope that our members can continue to engage with the regulator on a cooperative basis to ensure the ongoing development of our industry and the delivery of safe and effective animal health products to not only Australia but the world.³³

5.37 This view was not widely shared beyond industry representatives. A number of submitters and witnesses voiced concern about the regulator's lack of responsiveness to community concerns. For example, Gene Ethics advised:

We receive emails regularly from them [APVMA] about gazettals of changes to things like maximum residue levels and the introduction of new active ingredients. You can make comments; you get no feedback. Certainly an exchange of information and views is important. There are no forums for doing that...It appears that the advisory bodies do not include public interest representatives, and I think anybody who's advising regulators should necessarily have, as part of its membership, those interested and informed members of the community who have the expertise, the time and the energy to make input.³⁴

5.38 Friends of the Earth Australia gave evidence that the APVMA had previously been more responsive to community views. An APVMA advisory board and community consultative committees provided a means through which community concerns could be expressed and considered. However, both were abolished. According to Mr Anthony Amis of Friends of the Earth Australia, there was no explanation offered when the APVMA advisory board was abolished in 2015 and members of the APVMA community consultative committees were not provided any rationale when the committees were shut down in 2012. He concluded that the APVMA has moved backwards in terms of its engagement with the community and that the regulator demonstrated an unwillingness to disclose its work to a wide section of the community.³⁵

5.39 The National Toxics Network echoed this view and emphasised the importance of consultation:

When we had greater access to the APVMA and their staff, when they had advisory committees, we used to have a lot more robust discussions. But

33 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 7 December 2018, p. 32.

34 Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 21–22. See also: Ms Ruth Weston, *Submission 4*.

35 Mr Anthony Amis, Pesticides and Drinking Water Campaigner, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 53.

since those committees no longer exist, we actually find it much more difficult to raise our concerns in a productive way with the APVMA. However, on occasions, when we are discussing certain issues, there are certain members of staff who are willing to talk to us on the phone and to provide their perspective, which is helpful.³⁶

5.40 The Committee heard there appeared to be an imbalance between the APVMA's consultations with industry and its consultations with community groups. For instance, Friends of the Earth Australia referenced evidence from DAWR with regard to the proposed APVMA governance board and told the Committee:

It says that there were 13 meetings with industry—either CropLife or other representatives of the agrochemical industry—and I note that there were absolutely no meetings with any public health experts, any environmental groups or any risk assessment experts. In that document it talks about lowering the costs of doing business and reduced regulatory burden. We're really concerned that this seems to be a consistent emphasis, and I notice in the APVMA's reporting on its performance that it all seems to be about rushing as many chemicals through as quickly as possible. That's how they're recording their performance.³⁷

5.41 Some submitters called for community representation on the proposed governance board for the APVMA.³⁸ The legislation for the APVMA board was introduced in the Senate in September 2018 as an amendment to the *Agricultural and Veterinary Chemicals Legislation Amendment (Operational Efficiency) Bill 2017*. According to DAWR, the purpose of the board would be to:

- ensure the proper, efficient and effective performance of the APVMA's functions;
- determine the policies, objectives and strategies to be followed by the APVMA; and
- be the accountable authority under the *Public Governance, Performance and Accountability Act 2013*.³⁹

36 Ms Joanna Immig, National Coordinator, National Toxics Network Inc, *Committee Hansard*, 7 December 2018, p. 26.

37 Ms Louise Sales, Emerging Tech Coordinator, Friends of the Earth Australia, *Committee Hansard*, 7 December 2018, p. 52. See also additional information: Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

38 For further information on the proposed governance board, see: Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

39 Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

5.42 The Government's intention was for the board to be skills-based, and to comprise five members: the chair, three board members, and the APVMA CEO as an *ex officio* member.⁴⁰

5.43 With regard to representation on the board, a number of environmental and community groups advocated for wide representation beyond the industry. Ms Immig from the National Toxics Network expressed the view that any proposed governance board should contain members outside of industries 'that want to sell or benefit from the use of those chemicals'. Noting that the core business of the APVMA is to protect health and the environment in relation to pesticides use, she argued in favour of appointing board members who represented those sectors.⁴¹

5.44 In terms of engaging with the community, the Committee found that the APVMA does, as part of its reconsideration powers under the Agvet Code within the Agvet Code Act, invite any person through a public invitation notice to propose active constituents, chemical products, or labels for chemical reconsideration. A person proposing a chemical/product or label for reconsideration must submit reasons (based on the statutory criteria of safety; efficacy; trade; labelling; or a subset determined by the APVMA) for the proposal.⁴²

5.45 Further, the APVMA is required to make efforts to ensure its process for reconsideration is transparent. When commencing a chemical reconsideration, the APVMA prepares and publishes on its website, a work plan that provides information on the specific process. This includes expected dates for information requests and opportunities for interested parties to contribute to the reconsideration.⁴³

5.46 When making a decision in a chemical reconsideration, the APVMA must have regard to:

- the information given to it in response to notices or invitation for comment;
- the results of trials it required holders to conduct;
- information it has received independent of the chemical reconsideration that would suggest one or more of the safety, efficacy, trade or labelling criteria may not be met; and
- any other information it deems necessary.⁴⁴

40 Department of Agriculture and Water Resources, Inquiry into the Independence of Regulatory Decisions Made by the Australian Pesticides and Veterinary Medicines Authority (APVMA): APVMA Governance Board, additional information received 22 November 2018.

41 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, pp. 29-30. See also: Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, pp. 21–22.

42 Department of Agriculture and Water Resources, *Submission 9*, p. 2.

43 Department of Agriculture and Water Resources, *Submission 9*, p. 2.

44 Department of Agriculture and Water Resources, *Submission 9*, p. 3.

Consultative forums

5.47 Regulators overseas have adopted various models to engage with and address community concerns. Two such models are the UK Pesticides Forum and the US EPA Pesticide Program Dialogue Committee (PPDC).

UK Pesticides Forum

5.48 In 1996, the UK Government established the Pesticides Forum to engage a range of organisations interested in how pesticides were used and the impact of their use. In 2013, under the European Union mandated *UK National Action Plan for the Sustainable Use of Pesticides*, its role was expanded to provide for stakeholder interaction and an annual report on developments in the action plan.⁴⁵

5.49 Other than maintaining stakeholder oversight of the UK National Action Plan, the Forum aims to monitor the effects of policies, laws and other initiatives that affect or are affected by the use of pesticides, and offer advice to ministers and stakeholders as appropriate. It is a forum for exchanging views, and wherever possible, allowing stakeholders (people with an interest in the work of the Forum) to come to a general agreement.⁴⁶

5.50 The Forum's terms of reference are to:

- bring together the views of those concerned with the use and effects of pesticides and identify their current interests;
- assist in the effective dissemination of best practice, advances in technology and research and development in results; and
- advise government on the development, promotion and implementation of its policy relating to the responsible use of pesticides.⁴⁷

5.51 The Forum also works to a series of objectives around communication, impact monitoring, and knowledge transfer. It has three groups, which examine specific sectoral issues: Grower Liaison; Amenity Use Liaison; and Amateur (home and garden) Liaison.⁴⁸

45 Health and Safety Executive, *Pesticides Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/grouphome> (accessed 2 January 2019); Department for Environment, Food & Rural Affairs, *UK National Action Plan for the Sustainable Use of Pesticides (Plant Protection Products)*, February 2013.

46 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

47 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

48 Health and Safety Executive, *About the Forum: Pesticides Forum Aims, Objectives and Terms of Reference*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

5.52 The Forum intentionally includes stakeholders with differing views about pesticides and how the impacts of their use should be addressed. Member organisations, of which there are currently 26, include those who make, use or advise on pesticides as well as environmental, conservation and consumer interest groups. Membership covers the farming (conventional and organic production), farming equipment and pesticide industries; environmental and conservation groups; education and training; consumer interests and trades unions. Representatives from all UK government departments responsible for, or interested in, pesticides in the UK also participate in meetings.⁴⁹

5.53 The Forum provides a mechanism for exchanging ideas, encouraging joint initiatives to address particular issues and giving advice to Government on practical aspects of pesticide usage.⁵⁰ Minutes from the meetings of the Forum are publicly available, as are a range of papers and presentations.⁵¹

Environmental Protection Agency: Pesticide Program Dialogue Committee

5.54 The Pesticide Program Dialogue Committee (PPDC) was established in 1995 as a forum for stakeholders to provide policy advice, information and recommendations to the EPA on a range of pesticide regulatory, policy and program implementation issues, but specifically on:

- developing practical, protective approaches for addressing pesticide regulatory policy, program implementation, environmental, technical, economic and other policy issues; and
- reviewing proposed modifications to the EPA's Office of Pesticide Programs' current policies and procedures, including the technical and economic feasibility of any proposed regulatory changes to the current process of registering and re-evaluating pesticides.⁵²

5.55 The EPA selects members of the PPDC, of which there are currently 37, to represent a diverse group of stakeholders. Members are drawn from pesticide user, grower and commodity groups; consumer and environmental public interest groups; farm worker organisations; pesticide industry and trade associations; state, local and

49 Health and Safety Executive, *About the Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=36915&exp=e1> (accessed 2 January 2019).

50 Health and Safety Executive, *Pesticides Forum*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/grouphome> (accessed 2 January 2019).

51 Health and Safety Executive, *Forum Meetings*, <https://webcommunities.hse.gov.uk/connect.ti/pesticidesforum/view?objectId=37683&exp=e1> (accessed 2 January 2019).

52 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019); United States Environmental Protection Agency, *Pesticide Program Dialogue Committee Charter*, <https://www.epa.gov/sites/production/files/2018-04/documents/ppdc-2017-renewal-charter.pdf> (accessed 11 January 2019).

tribal governments; federal government; academia; the general public; and public health organisations.⁵³

5.56 Topics discussed at meetings vary, but have included the following:

- regulatory issues such as registration, reduced risk pesticides, labelling, fees, experimental use permits, environmental marketing claims, pollinator protection;
- science issues including toxicology, non-animal testing and ecological standards; and
- a range of other topics like integrated pest management, public health, spray drift, antimicrobial pesticides, engendered species, minor uses, and public engagement.

5.57 The PPDC is permitted, with the EPA's approval, to form subcommittees or workgroups for any purpose consistent with its charter. It currently has two active workgroups: pollinator protection plan metrics; and public health. Records from 16 previously active workgroups are available on the EPA's website.⁵⁴

5.58 The PPDC meets twice a year and its meetings are open to the public. Meeting papers are published on the EPA website. Members of the public are encouraged to contribute to each meeting during the comment session or by submitting comments prior to the meeting.⁵⁵

5.59 The EPA identified the PPDC as an important way to ensure the inclusion of stakeholders in its scientific and policy decisions.⁵⁶

Liaison between industry and APVMA

5.60 In addition to providing for more formal engagement between the APVMA and community groups, the Committee was provided with evidence about the importance of facilitating contact between industry and the regulator. A number of stakeholders expressed their strong support for organised interactions between industry and the APVMA, as had occurred previously on both a formal and informal basis.

53 United States Environmental Protection Agency, *Submission 109*, p. 2; United States Environmental Protection Agency, *Pesticide Program Dialogue Committee Charter*, <https://www.epa.gov/sites/production/files/2018-04/documents/ppdc-2017-renewal-charter.pdf> (accessed 11 January 2019); United States Environmental Protection Agency, *Pesticide Program Dialogue Committee—Roster 9/12/2018*, <https://www.epa.gov/sites/production/files/2018-09/documents/ppdc-roster-9-12-2018.pdf> (accessed 11 January 2019).

54 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019).

55 United States Environmental Protection Agency, *Pesticide Program Dialogue Committee (PPDC)*, <https://www.epa.gov/pesticide-advisory-committees-and-regulatory-partners/pesticide-program-dialogue-committee-ppdc#about> (accessed 11 January 2019).

56 United States Environmental Protection Agency, *Submission 109*, p. 2.

5.61 Greater industry involvement, including in the development of policies on the responsibilities of the industry sector and national regulators, was suggested by Grain Producers Australia. The organisation stated such work was supported by the Strategic Approach to International Chemicals Management under the United Nations Environment Program, which aimed to promote chemical safety around the world.⁵⁷

5.62 The NSW Farmers' Association agreed industry engagement with the APVMA was appropriate to 'ground-test the agency's work' and to ensure safe chemical use, for instance, to test if there was a 'proper understanding of APVMA labelling'.⁵⁸

5.63 Veterinary Manufacturers and Distributors Australia identified the need for contact between the regulator and industry, particularly in understanding the organisation's procedures and requirements:

We are invited to become involved in situations where the regulator is trying to improve its processes, such as clarity around the top 20 project, which is a means of trying to set standards and/or procedures that will make it clearer and more certain as to what is required...it's a little bit like a maze where you run into a brick wall with an application and all you can do is back up and start again. There's no clear overview of where an application will go.

To be fair to the APVMA, they are working on developing such a thing. The industry—our body and others—are involved in that so that there will be some sort of clear critical path or Gantt chart that will show you, 'At this point you will need X information,' which at least would allow you to say, 'If we can't get that information, there's no point in proceeding with this application.' At the moment, the formal procedure is to just put it in and wait for a brick wall to be thrown up.⁵⁹

5.64 The benefits of industry and the APVMA working together were also identified by Horticulture Innovation, with Ms Jodie Pedrana remarking that the APVMA had offered considerable guidance, particularly about the data required to support an application for a permit. She explained that the APVMA had helped and guided Horticulture Innovation in order that it could undertake the required residue data, efficacy data or crop safety data required to make an application more successful and to protect industries and consumers in the process. Ms Pedrana also remarked of the APVMA:

They've communicated different areas to our growers continuously to inform them of decisions that might impact them with regard to reviews...It

57 Grain Producers Australia, *Submission 11*, p. 5.

58 NSW Farmers' Association, *Submission 8*, p. 12.

59 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 7 December 2018, p. 33.

takes time to generate the data, and they've guided us through that process so we can be successful.⁶⁰

5.65 Industry stakeholders spoke highly of the broader assistance APVMA scientists provided to industry. For example, Cotton Australia stated:

On the resistance management plan...our scientists did a lot of work and set up some tactics that farmers have to carry out if they grow a genetically modified cotton crop, and those tactics were developed in consultation with the owners of the GM product, with our farmers in the industry and with the APVMA, so it's a process where we all work together with the best possible science to put these robust processes in place to stop resistance developing to the insects. You've got this situation where the protein or the chemical that's killing the insects is actually in the plant, so there is a high chance that you could get resistance unless you have these strategies. We work with the APVMA to do that. As Dr Taylor said, there are now published scientific papers out there that hold Australia up as the glowing example of how to do this, how to have these tactics that maintain the GM crop and stop resistance developing. So it is a really important role that the APVMA has played...a very important role in working with the proponents and with industry to get that right, because that is, if you like, on the label. This resistance management plan is something legally the farmers have to comply with.⁶¹

5.66 While there was general agreement that the formal consultation processes of the past were beneficial to a wide range of stakeholders, the Committee was cautioned that they should not be reintroduced without prior consultation and improvement. For example, the Veterinary Manufacturers and Distributors Association explained that the former formal industry liaison committee was not well designed. Mr Jim Adams, Executive Director noted that the APVMA had 'shoe-horned all of its technical people into the industry liaison committee'. He continued:

We had a table like this and quarterly meetings, and we tried to talk about policy with 20 different opinions in the room, some from organisations with a broad view and others from people...who have one single issue with one single product.⁶²

60 Ms Jodie Pedrana, Research and Development Manager, Horticulture Innovation Australia, *Committee Hansard*, 20 November 2018, p. 27.

61 Mr Adam Kay, Chief Executive Officer, Cotton Australia, *Committee Hansard*, 20 November 2018, pp. 50–51.

62 Mr Jim Adams, Executive Director, Veterinary Manufacturers and Distributors Association, *Committee Hansard*, 7 December 2018, p. 33.