

Chapter 4

Chemical reconsideration and innovation

4.1 The APVMA has a formalised process for chemical reconsideration and a program for chemicals subject to review that is based on assessment of risk, rather than a pre-determined schedule. The risk principle establishes a balance between protecting community safety and maintaining access to safe and effective chemicals.

4.2 The APVMA's reconsideration of glyphosate, a chemical that is commonly used and essential to current farming methods in Australia, has been subject to intense scrutiny, particularly in response to a perceived disagreement with the evaluation undertaken by the International Agency for Research on Cancer (IARC). While the APVMA's chemical risk and weight-of-evidence approach contrasts with the IARC's hazard-based assessment, perceptions of a disagreement between the two demonstrate the challenges for the APVMA in educating and informing the general public of its approach.

4.3 The case of glyphosate has also raised the issue of alternative chemical use and the barriers to innovation and investment for the Australian market for Australian-specific pests. This chapter explores the chemical review process and evidence provided to the committee in relation to it.

Reconsideration (chemical review)

4.4 The APVMA has a legislated process, through its Chemical Review Program, to undertake a formal chemical review (or reconsideration) of active constituents after they have been approved or registered in Australia. This allows the authority to take into consideration new and/or emerging scientific information that could change the approved chemical's risk to human health, the environment, animal or crop safety, or trade. Typically, an APVMA review might focus on one or more areas, including environmental safety, worker safety, public health, residues, trade or efficacy.¹

4.5 A formal reconsideration process, under the Chemical Review Program, is initiated when new scientific information raises concerns relating to the safety or effectiveness of a pesticide or veterinary medicine. It incorporates legislative, administrative and scientific elements, which inform a final decision to affirm, vary, suspend or cancel an approval or registration.²

4.6 The APVMA observed that the process could be complex, requiring significant organisational resources and time. During the assessment phase of a reconsideration, companies must submit a range of data, which might include

1 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018); Australian Pesticides and Veterinary Medicines Authority, *Submission 7*, p. 2.

2 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018).

laboratory studies, the results of field trials, target animal or crop studies and human studies. These are scientifically assessed. Under current legislation, reconsiderations must be completed within a maximum timeframe of 57 months.³

4.7 The Committee received evidence that this timeframe was not always met. For example, the National Toxics Network stated the chemical chlorpyrifos had been under review by the APVMA for 22 years.⁴

4.8 The Australian Food Sovereignty Alliance also raised concerns with reconsideration timeframes and processes, stating:

Despite there being hundreds of chemicals on the market, the APVMA has only prioritised five chemicals for reconsideration in the next 5 years. And of the 11,700 toxic pesticides registered, only 13 are being reviewed. In terms of timeliness...a review of Chlorpyrifos began in 2009, Diazinon in 2003, and Paraquat 1997, but all are incomplete. By contrast, APVMA has completed assessment of 757 new chemical applications since September 2018.⁵

4.9 The APVMA acknowledged its chemical review program was behind schedule, but told the Committee that the risks were being managed. Dr Parker, CEO of the APVMA, explained:

It is routine for the APVMA to take interim regulatory action in the early stages of a chemical review to suspend registration, remove uses or adjust label directions as a precaution. It is also common for us to reinstate uses once they've been assessed by additional data that is provided throughout the review process and that is finalised in our regulatory decision. We did this with dimethoate, diuron and [f]enthion. This is the system working as intended. It balances the spectrum of community, user and industry perspectives by applying the scientific evidence to what can only be at times an emotive debate over the safety of agriculture and veterinary chemicals.⁶

Chemicals subject to review

4.10 Over 5,000 agvet chemical products currently available in Australia were registered under prior legislative arrangements, often involving less rigorous assessments, some of which date back to the 1950s. These chemicals, previously approved by the states and territories, were grandfathered into the NRS in 1995. The development of the NRS came out of a 1991 agreement between the Commonwealth,

3 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018); Australian Pesticides and Veterinary Medicines Authority, *The Reconsideration Process*, <https://apvma.gov.au/node/10966> (accessed 4 January 2018).

4 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, pp. 26, 28.

5 Australian Food Sovereignty Alliance, *Submission 90*, pp. 13–14

6 Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

states and territories to place under one national umbrella the assessment and registration of all agvet chemical products, which had hitherto been undertaken independently by the Commonwealth and each of the states and territories.⁷

4.11 Initially over 300 chemicals on the NRS were nominated by stakeholders as potential candidates for review. Ultimately, a priority list of 80 was established. In the years since the Chemical Review Program has been operating, an additional 80 chemicals have been nominated and prioritised for inclusion on the review list with the original 80 chemicals. Of the chemicals on the review list, 75 had been completed by 2014.⁸

4.12 The APVMA's process to identify and nominate chemicals for review remains ongoing. In 2015, the APVMA consulted the public, industry and federal and state government agencies on the prioritisation of 19 chemicals (or types of chemicals) it had identified for review. Five chemicals were prioritised for detailed scoping with the remainder prioritised once the first five had been commenced.⁹

4.13 The Committee heard evidence that between 20 and 30 chemicals currently sold in Australia had been either banned by other jurisdictions or were under serious review in other jurisdictions—some of which were grandfathered into the NRS.¹⁰

4.14 Bayer Crop Science responded to these claims and suggested that for insecticides and herbicides, 'there may be a difference between Europe and Australia', though they were not aware of any differences in registrations between the United States and Australia.¹¹

4.15 Bayer Crop Science went on to suggest that the differences in registration could depend on the types of data requirements of regulators:

In the EU right now, there's a guidance document that makes it extremely difficult to conduct the study in a way that can satisfy the requirements, so it's almost impossible to get through. That can raise an issue, whereas, in the risk based system that you have here in Australia or in the US or Canada, there are ways to tier those studies to make sure your product is

7 Productivity Commission, *Chemicals and Plastics Regulation*, July 2008, p. 209; Australian Pesticides and Veterinary Medicines Authority, *Legislative Framework*, <https://apvma.gov.au/node/4131> (accessed 10 January 2019).

8 Australian Pesticides and Veterinary Medicines Authority, *History of the Chemical Review Program*, 1 July 2014, <https://apvma.gov.au/node/10971> (accessed 19 December 2018); Ms Kareena Arthy, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Estimates Hansard*, 29 May 2014, p. 104.

9 Australian Pesticides and Veterinary Medicines Authority, *Chemicals Nominated and Prioritised for Reconsideration*, <https://apvma.gov.au/node/10876> (accessed 4 January 2019).

10 Ms Joanna Immig, National Coordinator, National Toxics Network, *Committee Hansard*, 7 December 2018, p. 29.

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

safe, can be used safely and won't harm the environment but also is going through a reasonable scientific assessment.¹²

Differences between jurisdictions—risk and scheduled review

4.16 International regulators may use periodic reviews to conduct a re-evaluation of chemicals from first principles against contemporary standards, or target re-evaluations based on new information that addresses regulatory standards introduced since initial registration.¹³

4.17 For chemical review, other national regulators often operate under either risk-based principles or legislated timeframes. For instance, the Canadian PMRA has a legislated 15-year re-evaluation cycle to ensure products meet the latest health and environmental risk assessment standards. The European Union combines a risk-based approach with a maximum review period of 15 years. The United States Environmental Protection Agency (EPA) has a 15-year review period. Brazil has a risk-based approach.¹⁴

4.18 The APVMA's review program is risk-based. A review is considered when new scientific information becomes available that suggests there may be a change in the risk posed by a product. In 2013 and 2014, the authority was briefly required to conduct automatic reviews of all registrations according to certain specified timeframes. The 2013 Amendment Act inserted into the Agvet Code Act a requirement that the existing approvals and registrations of active constituents and chemical products operate for a finite period; and when that period elapsed, a new application was to be lodged for re-approval or re-registration.¹⁵ The *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Act 2014* repealed this provision.¹⁶

4.19 Many witnesses and submitters favoured a risk-based approach to re-evaluation.¹⁷ One consideration emphasised in submissions was the adverse consequences of the cost to industry of providing the information required by the

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

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

14 Reason Group, *Independent Review of Assessment Performance: Australian Pesticides and Veterinary Medicines Authority*, December 2017, pp. 37–55; Dr William Reeves, Health and Safety Issues Manager Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 6.

15 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*, *Bills Digest No. 93*, 2013–14, Parliamentary Library, Canberra, 2014, p. 3.

16 Paula Pyburne, *Agricultural and Veterinary Chemicals Legislation Amendment (Removing Re-approval and Re-registration) Bill 2014*, *Bills Digest No. 93*, 2013–14, Parliamentary Library, Canberra, 2014, p. 3.

17 See, for example: AUSVEG, *Submission 12*, p. [2]; CropLife Australia, *Submission 10*, p. 13; Western Australian Farmers Federation, *Submission 15*, p. 2; National Farmers' Federation, *Submission 27*, p. [2].

regulator during the review process. These costs would be exacerbated if scheduled (rather than risk-based) reviews were enforced. DAWR stated the cost to industry in addressing a review had 'resulted in the withdrawal of some chemical products from the market in the absence of identifiable concerns for human, animal or environmental health'.¹⁸

4.20 This perspective, particularly in the case of chemicals with a small (yet important) market in Australia, was supported by the Australian Glyphosate Sustainability Working Group.¹⁹ Chemistry Australia also spoke in support of a risk-based approach, stating:

In the context of our economy and the size of our economy, a reconsideration process akin to what they have in the United States would be costly, cumbersome and probably not deliver a lot better outcome.²⁰

4.21 Mr Bernard Lee, Director of Policy and Regulation at Chemistry Australia further explained that in the United States, the fact that the chemistry is under constant review creates its own obstacle to market entry and can result in farmers potentially paying more for the chemical products. Mr Lee continued:

If you wanted to duplicate that in this country, the market size is not large enough to be having all of the companies involved generating data on an ad hoc basis for a chemical review program. It is far better that it be targeted at the risks associated. That's the beauty of the system we have—the regulator can respond. If it identifies concerns—if there are community concerns or if there are international developments that it becomes aware of—it can respond and place a chemical under review.²¹

4.22 The Australian Glyphosate Sustainability Working Group described the consequence of undertaking compulsory reviews of all products, and the impact these reviews would have on companies:

The APVMA is looking after hundreds of active ingredients and, if we were to have a review time frame that was too short, they'd be doing nothing but reviewing existing products, which would just waste everybody's time...One of the issues we have with reviews of agricultural products is that, once products are off-patent, companies are much less likely to do any work to protect those products in the marketplace because the return on the investment is going to be very small because you have a large number of generic players. So, part of the risk we would run in having a too tight or a too firm review process is that products which have been perfectly safe and with which we've had years and years of safe use would simply not be

18 Department of Agriculture and Water Resources, *Submission 9*, pp. 3–4.

19 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, pp. 13–14.

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

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

reregistered because nobody would present the data. They couldn't make any money out of doing so because of all the generic players in the marketplace. We have hundreds of generic players in the marketplace in Australia.²²

4.23 CropLife Australia also raised the workload associated with scheduled re-evaluation and drew upon the example of Canada, which has a 15-year re-evaluation for registered pesticides. It was noted that the re-evaluation workload was not sustainable, with the agency lacking resources to manage upcoming scheduled re-evaluations. The PMRA had almost double the staff of the APVMA. CropLife Australia also provided evidence of the regulatory burden of scheduled re-evaluations (and their delays) in the EU and the United States.²³

4.24 The APVMA, given the nature of the formal process, stated that it 'seeks to address regulatory issues pragmatically by exploring alternative regulatory and non-regulatory pathways before deciding to conduct a review'.²⁴

4.25 DAWR noted that although there were different triggers for regulatory reconsideration in other similar agencies located in international jurisdictions, once started, APVMA reconsiderations were 'comparable in their assessment rigour once evaluation has commenced'.²⁵

APVMA chemical risk approach

4.26 As with regulators in other countries, the APVMA undertakes a risk-based weight-of-evidence assessment to determining chemical risk.²⁶ A risk-based assessment includes a hazard assessment and an exposure assessment. It draws upon evidence reproduced independently by different researchers.²⁷

22 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 13.

23 CropLife Australia, *Submission 10*, pp. 13–15.

24 Australian Pesticides and Veterinary Medicines Authority, *Chemical Review*, 18 May 2016, <https://apvma.gov.au/node/10916> (accessed 19 December 2018).

25 Department of Agriculture and Water Resources, *Submission 9*, pp. 3–4. See also: United States Environmental Protection Agency, *Submission 109*, pp. 1–2.

26 The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) also adopts a risk-based approach. The United States Environmental Protection Agency uses a standard risk assessment procedure and a weight-of-evidence approach. Dr Brian Richards, Executive Director, Office of Chemical Safety, and Director, National Industrial Chemicals Notification and Assessment Scheme, Department of Health, *Committee Hansard*, 20 November 2018, p. 34; United States Environmental Protection Agency, *Submission 109*, pp. 3–4.

27 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

Risk assessment: hazard assessment and exposure assessment

4.27 A hazard assessment examines the data related to the intrinsic toxicity potential of an active ingredient and/or formulated product, and is the first step in determining whether a chemical poses an undue risk.²⁸

4.28 An exposure assessment involves an examination of the likely exposure of humans and environmental organisms to a chemical, and considers how the chemical product is intended to be used, the type and formulation of the product, and the crops or animals to be treated.²⁹

4.29 By combining these two elements, the APVMA assesses the likelihood and extent to which an adverse outcome would occur if the product was used according to the instructions on the approved product label.³⁰

Weight-of-evidence assessment

4.30 In a weight-of-evidence assessment, data is considered validated when it is reproduced independently by different researchers. This type of assessment considers the number of studies reporting a particular conclusion and the quality of the study design and data evaluation.³¹

4.31 Although there was significant support for the APVMA's chemical risk approach, several submitters were critical of it (for both initial assessment and reconsideration), calling instead for the introduction of a system based on the precautionary principle.³² Gene Ethics explained that in the European re-approval and re-registration process, which is based on the precautionary principle, 'if registrants do not come up with the evidence to show their products are safe, they are deregistered'.³³ This issue is discussed further in chapter 5.

Glyphosate

4.32 The case of the glyphosate re-assessment is illustrative of the broad range of factors that bear upon the work of chemical regulators.

28 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

29 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

30 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

31 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018).

32 Ms Ruth Weston, *Submission 4*, p. [1]; Local Environmental Action Forum, *Submission 14*, p. 1; Mr Duncan Mills, *Submission 20*, p. [1]; Friends of the Earth Australia, *Submission 35*, p. [2]; 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.

33 Gene Ethics, *Submission 40*, p. 1.

4.33 In 2015, the World Health Organization's IARC evaluated glyphosate as 'probably carcinogenic to humans'.³⁴ In the same year, the APVMA proactively self-nominated glyphosate for reconsideration.³⁵

4.34 The Committee was told there had been considerable community concern raised by the IARC report. The Australian Glyphosate Sustainability Working Group spoke of reactions within the agricultural community:

They [were] concerned about how this has happened, because they'd been told for years and years that glyphosate was safe, and suddenly here it was as a probable carcinogen and did they have to worry about it and those sorts of things.³⁶

4.35 More broadly, the Committee was informed that some local councils were reviewing their use or had stopped using Roundup (glyphosate) for weed management.³⁷ Some submissions to the inquiry drew on the IARC report to call for further examination of glyphosate while others called for it to be restricted or phased out on the basis that there remained too many questions as to the chemical's safety.³⁸ Gene Ethics was of the view that:

Overall it is fair to say that IARC conclusions call into question the safety of GBHs [glyphosate-based herbicides] beyond 'reasonable certainty of no harm'...To improve GBH safety standards...the following [should] be urgently undertaken...:

- human biomonitoring for glyphosate and its metabolites;
- prioritisation of glyphosate and GBHs for hazard assessments, including toxicological studies that use state-of-the-art approaches;
- epidemiological studies, especially of occupationally exposed agricultural workers, pregnant women and their children; and evaluations of GBHs in commercially used formulations, recognising that herbicide mixtures likely have effects that are not predicted by studying glyphosate alone.³⁹

34 World Health Organization International Agency for Research on Cancer, *IARC Monographs Volume 112: Some Organophosphate Insecticides and Herbicides*, July 2015, p. 78.

35 CropLife Australia, *Submission 10*, p. 11.

36 Dr Christopher Preston, Chair, Australian Glyphosate Sustainability Working Group, *Committee Hansard*, 7 December 2018, p. 10.

37 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

38 See, for example: Mr Robert Phelps, Executive Director, Gene Ethics, *Committee Hansard*, 7 December 2018, p. 19; Local Environmental Action Forum, *Submission 14*, p. 5; Mr Chris Anderson, *Submission 38*, p. [1]; Mr Richard Nankin, *Submission 77*; Australian Food Sovereignty Alliance, *Submission 90*, p. 27; Pesticide Action Group WA, *Submission 104*, p. 2.

39 Gene Ethics, *Submission 40*, pp. 9–10.

APVMA assessment of glyphosate

4.36 The APVMA commissioned the Office of Chemical Safety (OCS) within the Department of Health to undertake a two-phase review of the IARC report:

- phase 1: a preliminary scoping review of the IARC report to determine the relevance of the glyphosate classification as 'probably carcinogenic to humans' and the implications for glyphosate approvals and registrations in Australia; and
- phase 2: detailed assessment of studies identified during the phase 1 assessment which required further evaluation.⁴⁰

4.37 The APVMA also evaluated the studies referenced in the IARC report, as well as other studies and data, including recent international assessments of glyphosate undertaken by other regulators.⁴¹

4.38 The APVMA received 197 submissions during a consultation period on the proposed regulatory position report and the OCS reports between 30 September 2016 and 30 December 2016. Submissions were received from:

- representatives of growers who use glyphosate (2);
- representatives of non-government organisations (8);
- private business (1); and
- members of the public (186).⁴²

4.39 The APVMA noted that the majority of submissions received were beyond the scientific scope of the APVMA's assessment; and no new scientific evidence relating to the possible carcinogenicity of glyphosate not already considered by the APVMA was received during the consultation period.⁴³

4.40 In March 2017, the APVMA released its final regulatory position on glyphosate, which stated:

Based on this nomination assessment, the APVMA concludes that the scientific weight-of-evidence indicates that:

- exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans

40 Australian Pesticides and Veterinary Medicines Authority, *Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate*, March 2017, p. 8.

41 Australian Pesticides and Veterinary Medicines Authority, *Final regulatory position: Consideration of the evidence for a formal reconsideration of glyphosate*, March 2017, p. 8; Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

42 172 of these were generated from an online petition campaign. Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, pp. 9, 15.

43 Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, p. 9.

- there is no scientific basis for revising the APVMA's satisfaction that glyphosate or products containing glyphosate:
 - would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues
 - would not be likely to have an effect that is harmful to human beings
 - would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment
 - would be effective according to criteria determined by the APVMA by legislative instrument, and
 - would not unduly prejudice trade or commerce between Australia and places outside Australia.
- there are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration
- the APVMA will continue to maintain a close focus on any new assessment reports or studies that indicate that this position should be revised.⁴⁴

4.41 The APVMA responded to questions about the comprehensiveness of its re-evaluation of glyphosate during a public hearing. Dr Parker stated:

When the APVMA looked at the International Agency for Research on Cancer's report on glyphosate, we evaluated all 264 studies referenced in that report, plus further studies and data. We took the time to get the science right. We found that, on balance of scientific information, we did not have a need to change our stance on glyphosate.⁴⁵

4.42 Many submissions to the Committee supported the APVMA's assessment.⁴⁶ However, some interpreted it as contradicting the IARC findings (and other international evidence). A significant number of submitters argued there was

44 Australian Pesticides and Veterinary Medicines Authority, *Final Regulatory Position: Consideration of the Evidence for a Formal Reconsideration of Glyphosate*, March 2017, p. 9.

45 Australian Pesticides and Veterinary Medicines Authority, *Annual Report 2017–2018*, pp. 8–9; Dr Chris Parker, Chief Executive Officer, Australian Pesticides and Veterinary Medicines Authority, *Committee Hansard*, 20 November 2018, p. 2.

46 See, for example: CropLife Australia, *Submission 10*, p. 1; Western Australian Farmers Federation, *Submission 15*, p. 2; GrainGrowers, *Submission 23*, pp. 4–5; CropLife Australia *Submission 108 (Response)*; pp. 3–4; Agribusiness Australia, *Submission 30*, p. 6.

sufficient publicly available evidence that demonstrated the dangers of glyphosate, and that this evidence had been ignored by the regulator.⁴⁷

4.43 Academic and research scientist, Dr Ian Musgrave, indicated that he had examined the process used by the APVMA in its review and advised the Committee:

I checked the APVMA review against the similar reviews produced by the EFSA, the ECHA and the US EPA and compared what they reviewed, how they reviewed it and the depth of the review. My conclusion was that the APVMA had done a comparable job to other regulators in coming to their conclusion.⁴⁸

4.44 Bayer Crop Science gave evidence to the Committee that there was no engagement by Monsanto Australia with the APVMA as part of APVMA's review 'on any matters of substance'. However, there had been limited communication at relevant times about the APVMA's intentions for the review with regard to process and timing, and to clarify the scope of the review. Bayer Crop Science stated 'the review undertaken by APVMA was independent of any input from Monsanto Australia'.⁴⁹

IARC assessment

4.45 The IARC report (referred to as a monograph) on glyphosate was an evaluation of cancer hazard—defined as 'an agent capable of causing cancer under some circumstances'. This differed to an evaluation of cancer risk—defined as 'an estimate of the carcinogenic effects expected from exposure to a cancer hazard'.⁵⁰

4.46 The IARC emphasised the distinction between hazard and risk, stating that its *Monograph* publications 'identify cancer hazards even when risks are very low at current exposure levels'.⁵¹

4.47 The classification given by the IARC to a chemical is based on the strength of the evidence that an agent causes cancer. It is a measure of how confident the scientists who undertook the evaluation are that an agent causes cancer in humans. As a consequence, elements with different potencies can be placed in the same classification. The IARC cites the case of tobacco, plutonium, diesel engine

47 See, for example: Dr Alison Bleaney, *Submission 3*, p. 3; Ms Rosemary Mason, *Submission 5 (Attachment)*, p. 1; Local Environmental Action Forum, *Submission 14*, pp. 4–5; National Toxics Network, *Submission 24*, p. 5; Ms Jessica Harrison, *Submission 37*, p. [1]; Mr Chris Anderson, *Submission 38*, p. 1; Mr Richard Nankin, *Submission 77*, pp. 2–3, 14; M Oliver, *Submission 91*, p. [1]; Ms Patsy Lisle, *Submission 92*, p. [1]; Ms Robin Thomas, *Submission 110*.

48 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 41.

49 Mr Tony May, Commercial Operational Lead, Bayer Crop Science, answers to questions on notice, 7 December 2018 (received 21 December 2018), p. 2. See also: Dr Nina McCormick, Regulatory Affairs, Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 4.

50 World Health Organization International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble*, 2006, p. 2.

51 World Health Organization International Agency for Research on Cancer, *IARC Monographs on the Evaluation of Carcinogenic Risks to Humans: Preamble*, 2006, p. 2.

emissions, hepatitis viruses and processed meat as having sufficiently strong evidence to classify them in the same group of cancer-causing agencies—group 1.⁵²

4.48 Given its stated purpose, the IARC report examined the intrinsic toxicity potential of glyphosate as a cancer-causing agent only. The IARC's evaluation consulted epidemiological studies that examined the circumstances under which human exposure occurs and at what levels. However, according to the APVMA, the assessment did not specifically consider risk management in actual use situations, nor did it examine the risk of cancer when glyphosate was used according to label instructions in a registered chemical product.⁵³

4.49 The IARC stated that identifying a carcinogenic hazard, based upon observable data, was a first step in risk assessment and management. It deferred risk assessment and risk management to national and international bodies; judging that risk assessment involved extrapolation beyond observed data, and risk management included social, economic and political considerations.⁵⁴

4.50 Dr Musgrave summarised the findings of the IARC report, observing:

The IARC concluded that glyphosate was a probable human carcinogen. They made that ruling independent of whether humans will be exposed to the levels of glyphosate that could potentially cause any form of cancer...it picks up hazards. Then it is up to the regulators...to make regulations based on their understanding of the data that the IARC brings forward.⁵⁵

Use of glyphosate in Australia

4.51 Bayer Crop Science estimated that around \$400 million of glyphosate-based products were sold in the Australian market each year—the largest selling agricultural chemical product on the Australian market.⁵⁶ The Committee was also told glyphosate had been crucial to growth in farming productivity in Australia's dry conditions.⁵⁷

52 World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 8.

53 Australian Pesticides and Veterinary Medicines Authority, *Glyphosate*, 13 September 2018, <https://apvma.gov.au/node/13891> (accessed 10 December 2018); World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 7; Dr Ian Musgrave, *Submission 41*, p. [3].

54 World Health Organization International Agency for Research on Cancer, *IARC Response to Criticisms of the Monographs and the Glyphosate Evaluation*, January 2018, https://www-prod.iarc.fr/wp-content/uploads/2018/07/IARC_response_to_criticisms_of_the_Monographs_and_the_glyphosate_evaluation.pdf (accessed 12 December 2018), p. 9.

55 Dr Ian Musgrave, *Committee Hansard*, 7 December 2018, p. 43.

56 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 4.

57 GrainGrowers, *Submission 23*, p. [7]; Agribusiness Australia, *Submission 30*, p. 5.

4.52 The Committee was advised that herbicides, including glyphosate, contribute to the preservation of soil health and stored carbon through their ability to facilitate no-till (or minimum till) farming practices; and through reducing chemical use in genetically modified canola systems.⁵⁸

4.53 Bayer Crop Science elaborated on what it saw as the benefits of glyphosate:

It really has enabled the uptake of zero-till farming, and, without those sort of practices, we wouldn't be able to store moisture over summer and we wouldn't be able to have more reliable cropping systems, and I think we've also seen higher yields. But we've also seen some environmental benefits around the reduction in tillage, and the reduction in wind and water erosion.⁵⁹

4.54 Around 85 per cent of growers in Australia were estimated by Grain Producers Australia to have adopted no-till production systems, one of the highest rates in the world.⁶⁰ Chemistry Australia gave evidence that glyphosate:

...has led to more sustainable agriculture, particularly the practices of minimum till. Minimum till reduces agricultural CO₂ emissions and it aids in the retention of soil moisture. Without advances like this from chemistry, we might well be sitting here today discussing the loss of Australia's prime agricultural land due to soil erosion.⁶¹

4.55 Grain Producers Australia also observed that 'farmers today are growing a lot more on a lot less moisture with the technology that's available to us. One of those key parameters for us is the use of glyphosate in terms of that minimum tillage and stored water'.⁶²

4.56 Given its centrality to contemporary farming methods, the Committee received evidence regarding the impact that the loss of glyphosate would have. The Grains Research and Development Corporation stated that, 'if glyphosate, for some reason, were no longer available and herbicide resistance continues to spread, it will cause pain to our grain growers'.⁶³ This was confirmed by GrainGrowers, which pointed out:

58 NSW Farmers' Association, *Submission 8*, pp. 12–13; Mr David McKeon, Chief Executive Officer, GrainGrowers Limited, *Committee Hansard*, 20 November 2018, p. 38.

59 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 2.

60 Dr Rohan Rainbow, Consultant Adviser, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 45.

61 Mr Bernard Lee, Director Policy and Regulation, Chemistry Australia, *Committee Hansard*, 7 December 2018, p. 46.

62 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 44.

63 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 31.

When we consider Australian grain farmers, we're talking about a group of a bit over 20,000 farm businesses who sustainably manage over 20 million hectares of Australian agricultural land, so there is a very large area that they look after and manage. And, if we think about those growers, if there were an immediate ban on, or removal of, glyphosate from the system, that would have absolutely catastrophic short-term impacts on Australian production systems.⁶⁴

4.57 AgForce Queensland agreed with other stakeholders about the significant consequences should glyphosate become unavailable, stating:

If, from public pressure and lack of trust, social licence caused the loss of glyphosate, the farming sector—our grain areas, our cane areas and all those areas—would no longer be able to do minimal till and no till. They would have to go back to tilling the land, which is digging up the soil, because minimum till and no till require herbicides to suppress the weeds, and that organic layer is keeping those soils protected until you plant your crop.⁶⁵

4.58 The NSW Farmers' Association described the potential impacts of removing glyphosate from agricultural activities and estimated that without glyphosate:

There would be an annual environmental loss associated with a net increase in the use of herbicides of 8.2 million kg of herbicide active ingredient (+1.7%), and a larger net negative environmental impact, as measured by the environmental impact quotient indicator of a 12.4%. Also, there would be additional carbon emissions arising from increased fuel usage and decreased soil carbon sequestration, equal to the equivalent of adding 11.77 million cars to the roads.⁶⁶

4.59 Many submitters and witnesses identified the lack of viable alternatives to glyphosate and the consequences for farming and food production should it become unavailable or banned in other jurisdictions.⁶⁷

4.60 The National Farmers' Federation contended that this was a particular concern for an industry that was export exposed.⁶⁸ AUSVEG noted the lack of alternative products, saying it would be 'catastrophic' to the industry if glyphosate were taken off the market.⁶⁹ Grain Producers Australia agreed, pointing out:

64 Mr David McKeon, Chief Executive Officer, GrainGrowers Limited, *Committee Hansard*, 20 November 2018, p. 39.

65 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, p. 57.

66 NSW Farmers' Association, *Submission 8*, pp. 12–13.

67 GrainGrowers, *Submission 23*, p. [7]. See also: Micro Survey Response—Glyphosate, attachment to GrainGrowers, *Submission 23*.

68 Mr Chris Groves, Chair, Farming Systems Committee, National Farmers' Federation, *Committee Hansard*, 20 November 2018, p. 15.

69 Mr Tyson Cattle, National Public Affairs Manager, AUSVEG, *Committee Hansard*, 20 November 2018, p. 53.

There are no other alternatives at the moment, which is a concern for industry. We don't have any other alternatives...The ability for us to produce as we do today will be reduced, because we won't have that alternative—we'll have to go back to tillage. Burning will become more of a consequence of that—that's one of the natural weed control methods that we still have today, but you will see a lot more concentration of that. You will also see us having to resort to using other products that we don't necessarily want to use, such as gramoxone and spray seed—those two particular products are S7 poisons. For farmers, they're products that we don't necessarily like to use...you would be going back to probably half of the current production area of cropping. So you take all those things into account, in a growing global climate of farmers right across the world having to do the same thing, and then we're in no-man's-land.⁷⁰

4.61 The trade impacts of glyphosate's removal were illustrated by Grain Producers Australia:

If consumers around the world banned glyphosate, particularly the European Union, that would have a big impact on our marketing of our grain into those particular markets...they're going to be asking us to do something that we cannot do in terms of our production system here in Australia. We will have no other alternative...⁷¹

4.62 The difficulty of finding viable alternatives to glyphosate was also made clear to the Committee. CropLife Australia remarked that 'even with US\$10 billion of research and development money each year, none of our members have come up with an alternative yet'.⁷²

4.63 However, some submitters contended that there were alternatives to glyphosate and other chemicals, and these could include: blade cultivation, rod and saturated steam weeding, swathng (for wet harvest), mechanical slashing, hand weeding, strategic plantings, and solarizing.⁷³

Innovation for Australian conditions

4.64 The glyphosate case raises concerns about the next generation of pesticides and veterinary medicines, particularly for a country like Australia that experiences specific conditions and represents a small market when compared globally.⁷⁴

70 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 44.

71 Mr Andrew Weidemann, Chairman, Grain Producers Australia, *Committee Hansard*, 20 November 2018, p. 45.

72 Mr Matthew Cossey, Chief Executive Officer, CropLife Australia, *Committee Hansard*, 20 November 2018, p. 59.

73 Mr Duncan Mills, *Submission 20*, p. [2]; Ms Jessica Harrison, *Submission 37 (Attachment)*, p. [1]; M and P Wilson, *Submission 108*, p. [3].

74 Mr David Mailler, Chair, Agricultural Science Committee, NSW Farmers' Association, *Committee Hansard*, 20 November, p. 16.

4.65 The growth of resistance to pesticides in some areas adds urgency to the situation. Apple & Pear Australia, for example, noted that resistance was becoming a more serious issue for its industry.⁷⁵ AgForce Queensland stated:

An increasing concern for AgForce is resistance of parasitic ticks to most acaricides and limited products for goat parasites. There is no interest from agvet chemical registrants to develop new products for use in Australia and no catalyst from Australian Government innovation programs to overcome pesticide resistance.⁷⁶

4.66 Associate Professor Christopher Preston also put forward his views on the role of pesticides, pointing out:

This reliance on pesticides has come at some cost. Pests are evolving resistance to pesticides requiring the adoption of new strategies for pest management and the need for new pesticides. On the other side, Australia is a relatively small market for pesticides. Internationally, there has been tremendous consolidation in the agricultural chemical space as companies merge. This has dramatically reduced the number of companies doing research and development on new pesticide molecules and frequently these molecules are being developed for large markets in Europe and North and South America and the main commodity crops grown in those locations.⁷⁷

4.67 Bayer Crop Science, which completed its acquisition of Monsanto in 2018, indicated that it spent approximately \$2.6 billion each year on research and development, yet:

The ability to find products has become harder and harder. Success in finding new compounds takes a lot more investigation and a lot more time, and there is a much greater cost to bring them to market than ever before.⁷⁸

4.68 Bayer Crop Science also noted:

Bringing new chemical compounds to market is now much more difficult than ever. Thirty years ago, an average of one in every ten thousand compounds that was tested could be developed for commercial release. Now the rate is only one in every fifty thousand.⁷⁹

4.69 Evidence provided to the inquiry indicated that Australia remains a low priority for chemical producers. For example, Grain Producers Australia commented:

Australia is no longer on the global priority list for pesticide and veterinary medicine investment in commercialisation as it was 20 years ago. Australia

75 Apple & Pear Australia Ltd, *Submission 31*, p. [1]. See also: Australian Food Sovereignty Alliance, *Submission 90*, p. 31.

76 AgForce Queensland Farmers Limited, *Submission 34*, pp. [4–5].

77 Associate Professor Christopher Preston, *Submission 19*, pp. [2–3]. See also: Gene Ethics, *Submission 40*, p. 5.

78 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, pp. 2–3.

79 Bayer Crop Science, *Submission 21*, p. 3.

is also missing out from productivity improvement through commercial investment in a large number of potential emerging biological, biochemical and biotechnology based AgVet technologies.⁸⁰

4.70 This point was echoed by AgForce Queensland:

Australia is only a very small part of the marketplace for most pesticides—I think just over 1.25 per cent of agvet chemicals internationally are used here—and most of our ticks are more an Australian pest; they're not in every other country. So, for a lot of the large pesticide companies, there is insufficient return on investment for them to work on a new active constituent or a new pesticide that would overcome these issues we get of pesticide resistance. Because there are millions of dollars that go into finding a product and doing all the necessary testing to be able to get it registered, unless a company knows it can forecast sales in that area, it's not willing to do that work.⁸¹

Australian conditions

4.71 The Committee heard there have been some programs that aim to address Australian-specific pest-management issues. One program run by the Grains Research and Development Corporation (GRDC) in conjunction with Bayer Crop Science has funded 33 postdoctoral positions to explore molecules effective in Australian conditions on Australian weeds. Under the partnership, postdoctoral students studied in Germany with Bayer Crop Science. The intent of the program was to put extra capacity into discovery for herbicides.⁸²

4.72 The GRDC reported that it had been working more broadly with the Bayer herbicide innovation platform so Australian weeds were included in initial screenings in herbicide discovery, including some resistant species. The early molecules were then brought to Australia and tested under Australian conditions against Australian weeds. According to the GRDC, part of the intention of the work with Bayer was to try to discover new chemistries that had the potential to replace chemicals like glyphosate.⁸³

4.73 Further, the GRDC has worked with the University of Western Australia under the Australian Herbicide Resistance Initiative to implement harvest wheat seed

80 Grain Producers Australia, *Submission 11*, p. 9. See also: Victorian Farmers Federation, *Submission 30*, p. [5].

81 Mrs Marie Vitelli, Biosecurity Policy Officer, AgForce Queensland Farmers Limited, *Committee Hansard*, 7 December 2018, pp. 59–60.

82 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, p. 17; Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 3.

83 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, pp. 30–31.

control. It was also investigating the use of microwaves and lasers, and the strategic use of tillage to control weeds.⁸⁴

4.74 Bayer Crop Science's Commercial Operations Lead, Mr Anthony May, argued that programs like the GRDC postdoctoral program had 'certainly elevated Australia and Australian weeds in that targeted area—where we might have been left behind—to larger markets, so I think it's been very effective in that way'.⁸⁵

4.75 The importance of understanding the operation of chemicals in specific conditions was highlighted by Associate Professor Susan Wilson. Noting that weed incursions into Antarctica and the sub-Antarctic are a considerable threat, she explained that there was a concern about the application of glyphosate in soils in that region when the research on it has been conducted with different soils and climatic conditions. Associate Professor Wilson continued:

There's been a little bit on cold climate in the Arctic, in the Northern Hemisphere. We've done a literature review in the first instance. As to how we test glyphosate in Macquarie Island soil, we bring back the actual soil and we specifically look at what would happen in the soil we're applying it to. We're subjecting it to the lower temperatures and where you might have higher persistence, a lot of rainfall and greater mobility. We're seeing whether that is the case or isn't the case for glyphosate in those systems so that, if a decision does need to be made regarding glyphosate use in weed management, the regulators have the science to make sound decisions.⁸⁶

84 Dr Ken Young, Crop Protection, Applied Research and Development, Grains Research and Development Corporation, *Committee Hansard*, 20 November 2018, pp. 30–31.

85 Mr Anthony May, Commercial Operations Lead, Bayer Crop Science, *Committee Hansard*, 7 December 2018, p. 8.

86 Associate Professor Susan Wilson, *Committee Hansard*, 7 December 2018, p. 17.